# THE GLOBAL ZIKA EPIDEMIC

## JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

AND THE

SUBCOMMITTEE ON THE WESTERN HEMISPHERE

OF THE

COMMITTEE ON FOREIGN AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

FEBRUARY 10, 2016

**Serial No. 114–184**

Printed for the use of the Committee on Foreign Affairs

Available via the World Wide Web: http://www.foreignaffairs.house.gov/ or http://www.gpo.gov/fdsys/

U.S. GOVERNMENT PUBLISHING OFFICE

98–600PDF WASHINGTON : 2016

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

## COMMITTEE ON FOREIGN AFFAIRS

EDWARD R. ROYCE, California, *Chairman*

CHRISTOPHER H. SMITH, New Jersey
ILEANA ROS-LEHTINEN, Florida
DANA ROHRABACHER, California
STEVE CHABOT, Ohio
JOE WILSON, South Carolina
MICHAEL T. MCCAUL, Texas
TED POE, Texas
MATT SALMON, Arizona
DARRELL E. ISSA, California
TOM MARINO, Pennsylvania
JEFF DUNCAN, South Carolina
MO BROOKS, Alabama
PAUL COOK, California
RANDY K. WEBER SR., Texas
SCOTT PERRY, Pennsylvania
RON DESANTIS, Florida
MARK MEADOWS, North Carolina
TED S. YOHO, Florida
CURT CLAWSON, Florida
SCOTT DESJARLAIS, Tennessee
REID J. RIBBLE, Wisconsin
DAVID A. TROTT, Michigan
LEE M. ZELDIN, New York
DANIEL DONOVAN, New York

ELIOT L. ENGEL, New York
BRAD SHERMAN, California
GREGORY W. MEEKS, New York
ALBIO SIRES, New Jersey
GERALD E. CONNOLLY, Virginia
THEODORE E. DEUTCH, Florida
BRIAN HIGGINS, New York
KAREN BASS, California
WILLIAM KEATING, Massachusetts
DAVID CICILLINE, Rhode Island
ALAN GRAYSON, Florida
AMI BERA, California
ALAN S. LOWENTHAL, California
GRACE MENG, New York
LOIS FRANKEL, Florida
TULSI GABBARD, Hawaii
JOAQUIN CASTRO, Texas
ROBIN L. KELLY, Illinois
BRENDAN F. BOYLE, Pennsylvania

AMY PORTER, *Chief of Staff* THOMAS SHEEHY, *Staff Director*
JASON STEINBAUM, *Democratic Staff Director*

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

CHRISTOPHER H. SMITH, New Jersey, *Chairman*

MARK MEADOWS, North Carolina
CURT CLAWSON, Florida
SCOTT DESJARLAIS, Tennessee
DANIEL DONOVAN, New York
KAREN BASS, California
DAVID CICILLINE, Rhode Island
AMI BERA, California

---

SUBCOMMITTEE ON THE WESTERN HEMISPHERE

JEFF DUNCAN, South Carolina, *Chairman*

CHRISTOPHER H. SMITH, New Jersey
ILEANA ROS-LEHTINEN, Florida
MICHAEL T. MCCAUL, Texas
MATT SALMON, Arizona
RON DESANTIS, Florida
TED S. YOHO, Florida
DANIEL DONOVAN, New York
ALBIO SIRES, New Jersey
JOAQUIN CASTRO, Texas
ROBIN L. KELLY, Illinois
GREGORY W. MEEKS, New York
ALAN GRAYSON, Florida
ALAN S. LOWENTHAL, California

# CONTENTS

# THE GLOBAL ZIKA EPIDEMIC

**WEDNESDAY, FEBRUARY 10, 2016**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS AND
SUBCOMMITTEE ON THE WESTERN HEMISPHERE,
COMMITTEE ON FOREIGN AFFAIRS,
*Washington, DC.*

The subcommittees met, pursuant to notice, at 1:15 p.m., in room 2172 Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations) presiding.

Mr. SMITH. The subcommittees will come to order and welcome.

In 1947, in a remote area of Uganda, scientists discovered a previously unknown virus among the rhesus monkey population. They called it the Zika virus for the forest in which it was found. It is endemic to Africa and to Southeast Asia. Scientists know that the Zika virus, like dengue fever and chikungunya, is spread almost exclusively through the bite of the Aedes species mosquito, an aggressive daytime biter. These mosquitos have been significantly diminished in this hemisphere, certainly in the United States, until the recent resurgence of dengue and chikungunya disease. We know a great deal about these disease vectors but there is much scientists admit they don't know about the Zika virus itself.

Lack of knowledge and misinformation has stoked apprehension and fear among many. According to the World Health Organization, some of the reasons why we don't know more about this disease include a relatively small proportion, about one in four, some say one in five, of infected people develop symptoms; a virus that is only detectable for a few days in infected people's blood; the failure of current test to definitively distinguish Zika from similar viruses such as dengue and chikungunya.

The World Health Organization recommends that all people in areas with potentially infected mosquitos, especially pregnant women, wear protective clothing and repellants and stay indoors to the extent possible with windows closed or screened. Pregnant women are urged to postpone travel to affected areas or to diligently protect against mosquito bites if travel is unavoidable.

Currently, no therapeutics exist to treat the Zika virus, nor is there a vaccine but that gap need not be forever. One of our distinguished witnesses today, Dr. Anthony Fauci, Director of NIH's Allergy and Infectious Disease Institute will explain the scope of NIH research on the Zika virus, as well as vector control. Surely lessons

learned from malaria vector control have applicability to Zika virus.

Our two other distinguished witnesses include Dr. Thomas Frieden, who has been here many times, so many times during the Ebola problem, and Ariel Pablos-Mendez, the Assistant Administrator for Global Health at USAID, who in like manor has been here and has done a wonderful job on all of these issues.

The U.S. Government has, for quite some time, promoted such tactics as insecticide-laced mosquito nets, window-endorsed screens, small pool and container drainage, and the use of strong but safe pesticides to eradicate mosquitos. However, our programs largely are tailored for developing countries. With the reemergence of dengue fever and chikungunya in the southern United States and in Hawaii, we have to step up our domestic efforts to control mosquitoes before warmer weather leads to an explosion of mosquito population during an imminent epidemic in the homeland.

According to Dr. Luiz Alberto Machado, Ambassador of Brazil, one of the areas most affected, and he is the Ambassador to the United States, the Brazilian Government has deployed 220,000 troops and 300,000 health agents to fight the vector of the infection by visiting communities to educate the population and help eliminate all mosquito breeding grounds. Experts cite possible links with the Zika infection of pregnant mothers and disorders affecting their unborn children, while they, including our witnesses today, are quick to point out that there is no definitive proof of such a linkage.

According to Brazil's Ambassador, and I quote him in part,

> Microcephaly in newborn babies can also be caused by a number of other diseases. Health experts are dealing with something new: the link between Zika and microcephaly is unprecedented in the scientific literature and requires in-depth studies and analyses . . . .

As a matter of fact, an AP story that just ran on February 6th points out that the President of Colombia has said that in all of their cases, there is not one case of microcephaly.

In fact, in announcing the administration's proposal for a supplemental sum of $1.8 billion to fund efforts to combat the Zika virus, the White House statement says that there "may" be a connection between the Zika virus and disorders experienced by newborns in affected countries.

Dr. Marcos Espinal, Director of Communicable Diseases and Health Analysis at PAHO, the Pan American Health Organization, said there is a broad spectrum of impacts for microcephaly from mild to severe.

A fact sheet on microcephaly in Boston Hospital's Children's Hospital notes that some children with microcephaly have normal intelligence and experience no particular difficulty with schoolwork, physical activity, relationships, or any other aspect of their lives. However, many children with the disease, especially those with more severe cases, face mild to significant learning disabilities, impaired motor functions, difficulty with movement and balance, speech delays.

In the meantime, we must work harder to prevent maternal infections and devise compassionate ways to ensure that any child born with disabilities from this or any other infection is welcomed, loved, and gets the care he or she needs. USAID's Ariel Pablos-Mendez will testify today that we need to expand best practices for supporting children with microcephaly. In like manner, parents of children with disabilities need to be tangibly supported as well.

Ana Carolina Caceres, a Brazilian journalist born with microcephaly, told the BBC's Ricardo Senra in a February 5th interview that the condition, and I quote her in pertinent part,

> is a box of surprises. You may suffer from serious problems or you may not . . . . On the day I was born, the doctor said I had no chance of survival. "She will not walk, she will not talk . . .". But he—like many others—was wrong. I grew up, went to school, went to university. Today I am a journalist and I write a blog . . . . People need to put their prejudices aside and learn about this syndrome.

This hearing will look into the implications of the current and long-term threat from the Zika virus, and we have assembled expert infectious health leaders from the Centers for Disease Control and Prevention, the National Institutes of Health, and the U.S. Agency for International Development to help us to understand where we are and where we go from here.

I will just note, parenthetically, that for more than 4 years, I have been urging passage of my bill the End Neglected Tropical Diseases Act and Dr. Pablos-Mendez has been very supportive and has testified at several hearings on this issue of neglected tropical diseases. The full Committee on Foreign Affairs approved it last month.

Since 2011, our committee has accelerated our discussions on the need for more study and funded efforts to identify tropical diseases and find diagnostics, vaccines and treatments of such illnesses. At that time, 2011, West Nile virus was quietly making its way across the globe, including the United States, from its origins in east Africa.

Ebola virus, first discovered in a remote area of central Africa in 1976, caused a global health crisis only 2 years ago.

And finally, and I say this with some concern, for the second consecutive year, the administration has slashed funding for global health accounts in the budget proposal released this week, including a 19-percent cut for global program on tuberculosis, the world's leading infectious disease killer. And I know that the three distinguished witnesses today, that is not your prerogative but that is what was sent up to Capitol Hill.

Additionally, the administration is being short-sighted with regard to neglected tropical diseases, cutting that program by nearly 15 percent. In the face of the waves of infectious disease epidemics in recent years, including multi-drug resistant tuberculosis, West Nile virus, Ebola and now Zika, the administration's disregard for this danger is simply inexplicable.

Zika has now joined the ranks of previously little-known diseases that have created global alarm. Before the next explosive health

crisis appears, we must provide sufficient resources to the study of tropical diseases.

I would note parenthetically, H.R. 1797 authorizes the creation of Centers of Excellence to study every aspect of these dreaded diseases. And I would note in the year 2000 and even most recently, just a few years ago, legislation that I authored on autisms created such Centers of Excellence at NIH and CDC and I think that has had a huge impact in combating that development disability. So, hopefully, we will get some traction on that legislation.

I would like to now yield to the distinguished chairman, my good friend, Mr. Duncan.

Mr. DUNCAN. I want to thank the chairman, Chairman Smith, for the joint hearing here and appreciate us being involved.

The Western Hemisphere Subcommittee is wanting to engaged in this issue because we are seeing this virus here and there is a lot of concern with the allies and neighbors in the region. Before 30 days ago, a lot of folks in my district never heard the words Zika virus. So, the Zika virus, virtually unknown in the Western Hemisphere until the first reported case was on Easter Island, west of Chile in February 2014. It has not exploded in the region with cases in 26 counties, territories, and the World Health Organization projecting Zika will likely spread to almost every single country in the Americas.

While symptoms for the majority of people who contract Zika are quite mild, the disturbing potential links of Zika causing microcephaly in unborn babies and GBS syndrome in some individuals has created panic around the region. Last month Brazil reported having over 4,000 suspected cases of microcephaly potentially linked to Zika as of October 2015. Although further investigation has confirmed microcephaly in just 400 of the suspected 4,000 cases, and only 17 of which tested positive Zika, concerns remain very real for pregnant women living in Zika-affected areas.

In addition, Brazil, El Salvador, Martinique, and Suriname have also reported an increase in GBS cases, potentially connected to Zika. Just last week, Colombia confirmed the first three deaths of patients infected with Zika who exhibited symptoms similar to GBS.

In May 2015, Pan American Health Organization issued an alert regarding the first confirmed Zika case in Brazil.

Last month, the U.S. Centers for Disease Control and Prevention issued a Level 2 alert warning to follow enhanced precautions for pregnant women and women of child bearing age and any travel to Zika-infected places. Subsequently, last week, the WHO declared the spread of Zika an international public health emergency and President Obama has since responded, the request this week for Congress to provide an additional $1.8 billion to address the Zika crisis.

I am deeply concerned about the impact that the Zika virus could have on women and future generations in Latin America and the Caribbean, where most of the population has little or no immunity, where mosquitos are simply part of everyday life, especially in poor communities, and where many governments' healthcare systems are not equipped to handle a mass influx of microcephaly or GBS cases as a result of the rising numbers of Zika cases.

In particular, Venezuela is reporting having over 4,700 Zika cases. With the lack of even basic healthcare options available due to horrible economic mismanagement, the Venezuela's ability to address rising numbers of Zika cases and provide the needed care for women in particular is severely in doubt and deeply worrisome, with some predicting that Venezuela could see the region's worst cases.

In contrast, Brazil, the host of this year's summer Olympics in August, has made huge efforts to curb the spread of Zika by fighting it with genetically modified mosquitos, deploying hundreds of thousands of troops to help educate the population about prevention, and working with the U.S. and international community to research the virus and development treatments.

Given the rapid spread of Zika virus in the Americas, several countries have tried to buy time to address the problems by urging women to postpone pregnancy. Colombia, Jamaica, Ecuador, and El Salvador have all issued these recommendations. However, while these governments may try to delay the spread of the virus through such announcements, many women unfortunately do not have the luxury of simply choosing to wait. Crime and violence plague much of the region. Corruption and impunity are endemic and women are often caught in the crosshairs, consequently facing unexpected pregnancies. As a result, the Zika virus has created a growing push for Latin American countries to liberalize their laws to allow greater access to contraception and abortion.

On February 5th, the U.N. High Commissioner for Human Rights called on Latin American countries affected by the Zika virus to increase this access. Today, Latin American countries have some of the strongest laws on the books protecting the life of the unborn. Chile, the Dominican Republic, Nicaragua, and El Salvador ban abortion completely, while only Uruguay and Cuba have legalized abortion, making it widely available. Other countries only allow abortion in the case of rape, incest, or the threat of the life of the mother. This push for more abortion access due to the potential birth defects from microcephaly is heartbreaking, especially since there are different degrees of microcephaly in some children born with these special needs may go on to live very normal lives. I think you gave a prime example.

Regardless, I believe every person, including the unborn child is made in the image of God and, therefore, has inherent worth. Thus, we must do everything we can to support the very real needs of women in Latin American and the Caribbean who are facing incredibly difficult situations, while also seeking to protect the lives of the unborn children.

So, in conclusion, it is my hope that our witnesses today will provide testimony of how the U.S. and countries around the world, especially here in the Western Hemisphere can fight and protect against the spread of Zika, while simultaneously working together to improve healthcare that address the needs of women, promotes life of the unborn, and improves therapy options for babies born with microcephaly and individuals affected with GBS.

And so with that, Mr. Chairman, I yield back.

Mr. SMITH. Chairman Duncan, thank you very much.

I would like to now yield to Dr. Bera.

Mr. BERA. Thank you, Mr. Chairman. Thank you for the timely hearing here. Obviously, this is an esteemed panel.

As a physician who has done public health work in Nicaragua in areas that we are finding endemic of certainly dengue fever when I was down there, but now it is Zika virus, this is going to be a challenge. Certainly, the mosquito we are dealing with is not an easy one to eradicate, not an easy one to prevent. But the purpose of this hearing is to make sure we get information out and also dispell misinformation. And in epidemics like this, that is incredibly important because lack of knowledge, because the spread of misinformation certainly can create panic and what we want to do is reassure the public that we are taking this outbreak and this epidemic very seriously but we are doing things in a responsible way.

I look forward to the testimony of our witnesses on how we are approaching this, the steps that we need to take, I applaud the President for his request of $1.8 billion, how we best can utilize those funds. But there is a lot that we don't know. I mean we have got to come up with more rapid diagnostic tests. We have certainly got to understand the extent of folks that are infected but also the fact that the vast majority of folks that do get infected probably are asymptomatic.

We also know that there is heightened risk in women of child bearing age and certainly women who are currently pregnant. We certainly want to hear the testimony of the witnesses with regards to what we can be doing. But as a physician, myself, certainly one thing we can do in endemic areas is liberalizing access to contraception, making sure that more women of child bearing age in endemic regions have access to full contraception. This isn't about abortion or not abortion. This is about making sure that those women who are not planning on getting pregnant have the ability to prevent that pregnancy, until we get a better understanding of what we are dealing with. And I would make a strong push in endemic countries to dedicate some of those resources to access to those family planning services, to access to contraception, to access to birth control, again, incredibly important.

For U.S. citizens that are planning on travel, obviously, if you are of child bearing age, we would urge you to take the caution. If you are pregnant, again, I would hear what those travel restrictions are but my sense is we would urge those women who are currently pregnant not to travel to endemic areas.

In addition, it is my sense that given the interconnectedness of the globe, we have started to see some Zika virus cases pop up in the United States. Epidemiologically I would be curious, my sense is these are generally folks who have traveled to endemic areas who are now returning. I would also be curious about the epidemiology in terms of where we are seeing the virus. It sounds like we may potentially be seeing it in semen. We may be seeing it in saliva and other bodily fluids; so, what we can do in terms of recommendations there.

Again, I applaud the panel here. Again, looking at this as a healthcare professional, I would urge that we don't panic. I would urge that we collect the data, the information. If folks are traveling to endemic areas, obviously, take the usual precautions to prevent

mosquito bites. If you are of child bearing age, certainly take those precautions. I would urge that we do use some of the resources that the President has requested to make access to full contraception more available for women of child bearing age in these endemic regions. That is one simple thing that we can do to prevent congenital abnormalities and so forth. And again, I don't think anyone argues that that isn't good medicine and good prevention.

So, again, I look forward to the testimony of the witnesses and, again, thank you, Mr. Chairman.

Mr. SMITH. Thank you very much.

I would like to now yield to the ranking member of the Western Hemisphere Subcommittee, my good friend from New Jersey, Albio Sires.

Mr. SIRES. Thank you, Chairman, and thank you for holding these hearings. I know how much you care about world health and people. And this certainly is a theme, a situation that we have to deal with right now.

You know the lack of clarity on the virus, and its effects, and its treatment make it all more important that we respond to this more aggressively than we have in some of the other diseases. I am very concerned now that we have the Olympics with our people going into Brazil. I think the Brazilian Government should be very concerned that a crisis doesn't spur because I don't think anybody would go to the Olympics if you have the situation where it gets to be panicking.

So, I want to hear what the panel has to say and I want to thank the chairman again and the ranking member for holding this hearing. Thank you.

Mr. SMITH. Thank you very much, Mr. Sires.

I would like to acknowledge Dina Fonseca, professor of entomology, ecology, and evolution at the Public Health Department at Rutgers in my home State of New Jersey. She is an expert on the mosquitos that carry Zika and other diseases and she has provided us some testimony that, without objection, will be made part of the record.

Introducing our very distinguished panel, beginning first with Dr. Tom Frieden, who has been the Director of the Centers for Disease Control and Prevention since June 2009 and has dedicated his career to fighting infectious and chronic diseases both here in the United States and abroad.

He led New York City's program that controlled tuberculosis, and reduced multi-drug resistant cases by 80 percent, and worked in India for 5 years helping to build a tuberculosis control program that saved nearly 3 million lives.

As the commissioner of New York City's Health Department, Dr. Frieden led programs that reduce illness and death and increase life expectancy substantially. He is the recipient of numerous awards and honors and has published more than 200 scientific articles.

We then go to Dr. Anthony Fauci, who is the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. Since his appointment to NIAID, Director in 1984, Dr. Fauci has overseen an extensive research portfolio devoted to preventing, diagnosing, and treating, infectious and im-

mune-mediated diseases. He has made numerous important discoveries related to HIV/AIDS, is one of the most cited scientists in the field.

Dr. Fauci serves as one of the key advisors to the White House and the Department of Health and Human Services on global AIDS issues and on initiatives to bolster medical and public health preparedness against emerging infectious disease threats, such as Ebola and pandemic influenza. He is also one of the principle architects of the President's Emergency Plan for AIDS Relief.

Then, we will hear from Dr. Ariel Pablos-Mendez, who is the Assistant Administrator for Global Health at USAID, a position he assumed in August 2011. Dr. Pablos-Mendez joined USAID's leadership team with a vision to shape the Bureau for Global Health's efforts to accomplish a measurable and sustainable impact in the lives of people in developing countries.

Before joining USAID, he worked on global health strategy and the transformation of health systems in Africa as well as Asia. He also served as Director of Knowledge Management at the World Health Organization.

Dr. Pablos-Mendez is a board certified internist and was a professor of clinical medicine and epidemiology at Columbia University.

Dr. Frieden, the floor is yours.

**STATEMENT OF TOM FRIEDEN, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. FRIEDEN. Thank you very much, Mr. Chairman, for calling this hearing. And thank you, Chairman Duncan, Dr. Bera, Ranking Member Sires for the opportunity to discuss Zika with you.

We look forward to a full and open discussion and I want to start at the outset with some basic facts. First, we are quite literally discovering more about Zika every single day. We are working around the clock to find out as much as we can, as quickly as we can, to inform the public and to do everything that we can do to reduce the risk to pregnant women.

Zika is new and new diseases can be scary, particularly when they may affect the most vulnerable among us. Right now the most important thing for Americans to know is this. If you are pregnant, we recommend you not go to a place where Zika is spreading. And if you are pregnant and you live in an area where Zika is spreading, do everything you can to protect yourself against mosquito bites.

The Aedes mosquito that spreads this particular virus is very difficult to control and I will talk about that more in a bit but it is a very important point, when we think about what we can do to respond to Zika in the short-term and in the longer term.

CDC is working 24/7 to get more information. We elevated our level of response on Monday of this week to Level 1, after your activation of our Emergency Operations Center last month. We are committed to continuing to share information as quickly as possible with the public and with healthcare providers and policymakers, so that people can make the best possible decisions about health based on the most recent and accurate data.

We will also continue to provide and update our guidance as soon as we know and learn more.

This is the latest in a series of unpredicted and, in many cases, unpredictable health threats and it emphasizes how crucially important it is that we continue to strengthen the systems that will find, stop, and prevent health threats, wherever they emerge around the world both the help other countries and to protect Americans here at home.

I want to start with what we know. As you said, Mr. Chairman, the virus was first identified in 1947. It was first identified to cause an outbreak and an outbreak that the CDC scientists investigated in 2007. It is believed to cause no symptoms in approximately 80 percent of the people infected and mild symptoms in virtually all of the rest. The mosquito that spreads it, the Aedes species. All right, there is the enemy. The Aedes aegypti mosquito is a very challenging, what we call, disease vector to control. It is an indoor biter. It bites all through the day, including at dawn and dusk. It hides in closets and under tables and places that are hard to get to. Its larvae or eggs, its eggs can be drought-resistant and can persist for some time. And it can bite four or five people in the course of one blood meal, meaning it can spread disease quite quickly. Our efforts to control it are challenging. It is hard to eliminate.

I want to show a bit about what has happened in recent years with dengue and chikungunya. These are two viruses spread by the very same mosquito as Zika is. In red on this map, you see the approximate geographic distribution of dengue around the world and you see that is widely distributed in that equatorial band, essentially above and below, throughout the world. Dengue has been increasingly present in recent years.

Now, if you look at chikungunya, chikungunya is spread by the same mosquito. It is a word that means bent over with pain. So, it can cause a severe, painful disease. And dengue, of course, can be very severe or fatal. And for more than 60 years, chikungunya was present in other parts of the world but not in our hemisphere. But over the past few years, it has spread widely within our hemisphere.

And these are the current known places where both dengue and chikungunya have been documented as spread. Anywhere either of these diseases is present, Zika may well follow in the coming weeks, months, and years.

Now, on microcephaly, this is an extraordinarily unusual event and I want to emphasize that. In 1941, scientists recognized that rubella causes the rubella syndrome. And with rubella vaccine, we have now virtually eliminated that in the U.S.

In 1962, scientists identified Cytomegalovirus, another virus, as a cause of severe fetal malformations. And in the past 50 years, we are not aware of any other viral cause of a significant number of birth defects. In fact, we are not aware of any prior mosquito-borne cause of fetal malformations, if in fact this is confirmed.

Guillain-Barre syndrome, which you have heard about, or a weakness after infections is a recognized complication of many different infectious processes, both bacterial and viral. It can occur in one in 1,000 or one in 100,000 people who have had an infection

and it increasingly looks like that it is associated with Zika virus infection as a post-infectious complication and it can be severe. But the big thing that is different here is the microcephaly.

Next, I would like to talk about what, based on what we know today, is likely to happen over the coming weeks and months and what we are doing about it to protect Americans. First, we will discover more each and every day. And I will show you later today some new data that was just released within the past hour. We will learn about maternal to child transmission, about any possible cofactors such as other infections, or nutritional factors that may increase or decrease a woman's likelihood of having the Zika infection transmitted to her fetus. We will learn about the relationship with both microcephaly and Guillain-Barre from studies that we are doing today with partners in Brazil, Colombia, Puerto Rico, and other places.

We will develop better diagnostics. Currently, we can diagnose the active Zika infection. And when someone is sick with Zika, we can find it in their blood. But if it is a couple of weeks or a couple of months later, figuring out if they have had Zika is very complex. And CDC scientists have worked for years to develop serological tests for that. We have a test but it is one that can have false positives for prior infection.

We will learn more about the level of risk, whether symptomatic Zika is more likely to cause other adverse health outcomes than asymptomatic Zika. We will learn more about how long a man who has been infected with Zika may continue to harbor Zika in semen and potentially spread it to sexual partners. We will learn more about how to optimally stop the vector, the mosquito that spreads Zika virus.

And for all of these things, we will need additional resources, which is why the emergency supplemental request is so important.

So, one thing that will happen is we will learn more. A second thing that will happen is we will see more cases among travelers to the U.S. Some of them will be pregnant and that is why we have issued travel advice not to travel if you are pregnant and we have worked with doctors, clinicians, and others to provide that advice.

Third, we will likely see significant numbers of cases in Puerto Rico and other U.S. territories, where there may be intensive spread of Zika. This is a particularly urgent area and I would like to show you a series of slides that show what happened in the chikungunya outbreak a little under 2 years ago.

On May 5, 2014, the first chikungunya case was identified in Puerto Rico. Two weeks' later, it had begun to spread and each of these slides is a 2-week period. Two weeks later, 2 weeks later, 2 weeks later, and by October, it was in almost all of Puerto Rico and has now affected at least a quarter of the adult population of Puerto Rico. So, this can spread very rapidly in a population.

We will move rapidly to support pregnant women and reduce the risk that pregnant women will become infected, to monitor and reduce mosquito populations to the greatest extent possible. And the next thing that we may see happen is cases or clusters in part of the U.S. that have had dengue clusters in the past. That is why we need support for local mosquito surveillance and control meas-

ures. We may also see sporadic cases elsewhere in the U.S. and, of course, unfortunately, continued spread around the world.

To finish what we are doing now is, in a whole of government way but with HHS as the lead, looking at what can be done to reduce the risk to pregnant women. And the CDC part of the supplemental request is $828 million to scale up prevention, both for pregnant women, for reducing the risk of mosquitos, to prevent transfusion, organ transplant, or other what we believe are rare potential forms of transmission and in the future, with NIH in the lead, vaccination.

To detect through laboratory tests, CDC laboratories have developed the diagnostics that are being used in this country and we are working around the clock to get these diagnostics out so that more people who want to be tested can be tested. We will improve clinical diagnosis and reporting, mosquito surveillance, and including the resistance of mosquitos to insecticides, which is very important to know so we can target our actions, and to understand microcephaly more.

Within the past hour, CDC has released information from Brazil on the findings among four infants, two miscarriages at age 10 and 11 weeks, spontaneous miscarriages, and two infants who tragically had microcephaly and died within the first 24 hours of life. And working with our Brazilian colleagues, the CDC laboratory was able to identify the genetic material of the Zika virus in the brain tissue of the two infants who died with microcephaly. This is the strongest evidence to date that Zika is the cause of microcephaly but it is still not definitive. We will still need to understand the clinical and epidemiological patterns to make that link definitive.

To do these investigations and to do the response, we will need additional resources. Vector control is complex and expensive. There are a series of measures we can take, particularly in the U.S. area of Puerto Rico and other parts that have had dengue transmission and we look forward to working with you to inform people about the latest information on Zika and what we can do to stop it.

So, thank you very much and I look forward to answering your questions.

[The prepared statement of Dr. Frieden follows:]

Statement of Thomas Frieden, MD, MPH, Director, Centers for Disease Control and Prevention
February 10, 2016
House Foreign Affairs Joint Subcommittee Hearing: The Global Zika Epidemic

Introduction

Good afternoon Chairman Smith, Ranking Member Bass, and members of the Subcommittee. Thank you for the opportunity to testify before you today and for your ongoing support for the Centers for Disease Control and Prevention's (CDC) work in global health. CDC works 24-7 to save lives and protect people against health threats. Today, I am here to discuss Zika virus in the Americas.

The Administration is taking every appropriate measure to protect the American people, and as you know on Monday announced that we are asking the Congress for more than $1.8 billion in emergency funding to enhance our ongoing efforts to prepare for and respond to the Zika virus, both domestically and internationally.

Zika is an emerging health threat and it is a rapidly changing situation involving many partners in this country and abroad. There are many things we don't yet know about Zika. We are figuring out more about Zika literally every day, and will share information – and adjust our guidelines and recommendations – as we learn more. That is the nature of a scientific response to an emerging health threat. The doctors, scientists, veterinarians, and others at CDC are working around the clock to protect Americans from this and other health threats. We already have made significant progress identifying the virus in brain tissue of affected infants, developing and distributing new diagnostic tests, issuing guidance, conducting epidemiological investigations along with affected countries, and improving monitoring and surveillance in the United States, including in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and American Samoa. Much of what we know about Zika and similar viruses today is based on the work done by CDC scientists who have dedicated their lives to working in this area. But

as hard as we work, there are still many things that we cannot know now, and cannot do now. We will continue to use the best of modern science to protect people as well as we can. I understand that Zika virus causes concern among people throughout the Americas, including people here in the United States. We are committed to ensuring that the American people have access to the most accurate, timely information about Zika virus and the current outbreak.

CDC is working in collaboration with other components of the Department of Health and Human Services (HHS), including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and within that the Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health, and the Food and Drug Administration, as well as with partners across the U.S. Government to communicate with health care providers and the general public; issue travel alerts and clinical guidance; and step up our efforts on research to better understand the Zika virus, and on the development of tests, treatments, and vaccines, as well as improved mosquito-control methods.

Zika and its History

Zika is a flavivirus, closely related to dengue, yellow fever, and West Nile viruses. Zika virus is primarily spread to people through the bite of certain infected *Aedes* species mosquitoes. These mosquitos also spread dengue, chikungunya, and other viruses. Mosquitoes become infected when they bite a person who is already infected with Zika virus. These infected mosquitoes can then spread the virus to other people through bites. Case reports of other modes of transmission include spread through sexual transmission and blood transfusion. Of great concern, Zika virus can also be passed from a mother to her developing baby during pregnancy.

Zika is not a new virus. It was first recognized in 1947, and it was recognized to cause occasional illness in Africa and Asia, but the first large outbreak we know of occurred in 2007 in the small Pacific island of Yap. Last May, the first local transmission of Zika in the Americas was reported in Brazil, and

by the end of 2015, Brazilian authorities estimated that the outbreak there involved perhaps a million suspected cases of Zika virus infection. In recent months, the virus has spread rapidly throughout Latin America and the Caribbean, as well as to parts of the Pacific. As of February 9, 2016, more than 30 countries and territories, including the Commonwealth of Puerto Rico as well as the U.S. Virgin Islands and American Samoa have reported local transmission of the Zika virus. On February 1, the World Health Organization (WHO) declared the recent cluster of microcephaly cases and Guillan-Barré, which has been temporally associated with Zika virus transmission, a public health emergency of international concern, a reflection of the seriousness of this unfolding health threat.

Symptoms and Adverse Outcomes

Most people who may be exposed to Zika virus will have only mild symptoms. In fact, about four out of five people infected with Zika appear not to have symptoms at all. Those who do become ill usually have mild symptoms such as fever, rash, joint pain, and red eyes or conjunctivitis. The symptoms last a couple days to up to a week, and it is very rare other than in utero, for Zika to cause serious illness or death.

Increasing evidence suggests that Zika virus infection may be associated with more serious health outcomes. In October 2015, Brazilian authorities recognized a concerning increase in microcephaly, which has occurred in close sequence to Brazil's outbreak of Zika virus. Microcephaly is a usually-rare, serious condition among newborns where a baby's head is smaller than expected when compared to babies of the same sex and age. Microcephaly is not a diagnosis in and of itself, but a sign that the brain did not develop as it should in the womb. Babies with microcephaly can have a range of problems, including seizures, developmental delay, feeding problems and hearing loss. In some cases, these problems can be life threatening.

Laboratory tests at CDC strongly suggest a link between Zika virus infection during pregnancy and microcephaly. We do not know whether this link is causal, or, if so, whether there are important

cofactors such as other infections, nutritional factors, or environmental toxins. We also do not know what, if any, other outcomes might be associated with Zika infection during pregnancy. Studies are in progress to learn more about the risks of Zika virus infection during pregnancy. Microcephaly in infants can be devastating to the affected families, and this ongoing outbreak is concerning to everyone, especially for pregnant women, and their families who may travel to or live in the infected areas. Zika virus spread in the Americas and its effect on pregnancy are new developments that we are working with partners to better understand.

Health authorities in Brazil and elsewhere have also reported an increase in suspected cases of Guillain-Barré syndrome, a rare neurologic disorder in which a person's own immune system damages nerve cells leading to nerve damage or paralysis that lasts for several weeks or several months. Most people fully recover, but it can take a few years to do so. Some people with Guillain-Barré syndrome have permanent damage and in rare cases, people have died. It is difficult to determine if any particular pathogen "caused" or "triggered" Guillain-Barré syndrome. Currently, we do not know if Zika virus infection causes Guillain-Barré syndrome. However, the development of Guillain-Barré syndrome is a recognized after-effect of many different infections, including infections with viruses similar to Zika. CDC is currently working with public health officials in Brazil to investigate whether there's any link between Zika infection and Guillain-Barré.

Preparedness and ResponseWe know that there will be many more Zika virus cases in affected areas in Latin America and the Caribbean. That is why the President's Zika emergency funding request includes support for CDC's efforts to enhance international capacity for virus surveillance, expand the Field Epidemiology Training program, laboratory testing, health care provider training, and vector surveillance and control in countries at highest risk of Zika virus outbreak.

While we have not yet seen transmission of the Zika virus by mosquitoes within the continental United States, we know that many returning travelers will have Zika infection – for comparison, there were 3,270 travelers in the United States diagnosed and reported with chikungunya infection in 2014 and 2015. So we expect that many travelers to the United States will be diagnosed with Zika infection, and the number of Zika cases among travelers visiting or returning to the United States will likely increase. Many areas of the United States have the type of mosquitoes that can become infected with and transmit Zika virus. Recent chikungunya and dengue outbreaks in the United States suggest that Zika outbreaks in the U.S. mainland may be relatively small and localized. Better housing construction, less crowding, regular use of air conditioning, use of window screens and door screens, and state and local mosquito-control efforts have helped to contain transmission of these mosquito-borne viruses. However, we understand that any local outbreaks will be of deep concern to the people living there. Furthermore, there is uncertainty surrounding the future, and it is important that we maintain and improve our ability to detect and respond to Zika and other mosquito-borne diseases. That is why the President's Zika emergency funding request includes support for Zika virus readiness and response capacity in States and territories with mosquito populations that are known to transmit Zika virus as well as to enhance mosquito control programs in these areas.For the Commonwealth of Puerto Rico as well as the U.S. Virgin Islands and American Samoa, the outlook is different. There have been case reports of local transmission in all three territories. Furthermore, recent outbreaks of dengue and chikungunya suggest that Zika virus may spread widely in those areas. Again, we appreciate the serious threat facing American citizens living in these territories and the emergency request would support targeted strategies to address these risks, and the entire Administration is committed to providing support to prepare and respond to this outbreak and to inform all Americans about how they may protect themselves from becoming infected with Zika virus.

Domestic Activities

CDC has a long history of assisting county, state, tribal and territorial public health partners to detect, prevent, and control diseases spread by mosquitos. Surveillance is essential to monitor and quickly identify areas with local transmission. We conduct multi-faceted surveillance for arboviruses, including Zika, through ArboNET, an integrated network which funds, through our Epidemiology and Laboratory Capacity cooperative agreements, staff in 49 states, Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitos, and perform laboratory analysis on arboviruses including Zika. Zika virus is now a nationally notifiable disease, meaning states report the virus to CDC, which will aid Zika surveillance efforts. CDC is also working with several states and Puerto Rico to determine a baseline prevalence of microcephaly so thatany an increase, should it occur, can be quickly and accurately identified.

With support from the President's emergency request, CDC will build on its current efforts to provide financial and technical resources to states and territories through cooperative agreements to strengthen their capacity to prepare for and respond to emerging threats such as Zika virus. These resources may be used to help health departments expand their capacity to prepare for cases of local Zika virus transmission in their areas and to implement community education and prevention programs to reduce human-mosquito contact and therefore reduce the risk of Zika transmission. Resources may also be used to implement vector control strategies to prevent further spread of Zika virus in areas where local transmission has been found.

It also is critical that states and territories are able to receive specimens and test for Zika virus in order to diagnose and report travel-related and locally acquired cases of Zika. CDC is providing, and under the emergency request will expand its efforts to assist public-health labs nationwide with the reagents necessary to test for Zika and the guidance on how to interpret test results. In addition, CDC is available to provide testing of any Zika samples upon request.

Building on experience applying advanced molecular detection technology to address the emergence of chikungunya virus, CDC scientists were able to develop, validate, and distribute a Zika test that could detect emerging strains for use in laboratories throughout the Western Hemisphere within three weeks of having received the first Zika virus sample. With older methods, this would have required three to four months. CDC also developed the IgM ELISA and Zika Virus Plaque reduction neutralization test in use at CDC to detect evidence of previous Zika infections. Currently, CDC scientists are also working to develop a faster, next-generation neutralization test that could detect prior Zika infection.
CDC experts are working intensively to learn more about the outbreak and provide people with the information they need to protect themselves. The same week the CDC laboratory identified Zika virus in samples from affected infants in Brazil, we issued a travel advisory indicating that pregnant women should consider postponing travel to Zika-affected areas. We issue travel alerts for the affected areas as confirmation of the virus is reported, and we'll keep you alert as the situation changes. Recognizing the potential for Zika virus transmission through blood transfusions, CDC is working with FDA to ensure the safety of the blood supply from Zika virus, particularly in regions experiencing local outbreaks. CDC also has provided guidance for doctors and other clinicians on evaluation, treatment and follow-up care of pregnant women and infants with possible exposure to Zika virus.

Our guidance has and will continue to be updated as our knowledge increases. As such, we have recently updated our guidance to provide recommendations for the clinical care and management of pregnant women living in areas where Zika transmission is widespread, with special consideration to the on-going risk of maternal Zika virus infection throughout pregnancy. These guidance documents were prepared in consultation with the American College of Obstetricians and Gynecologists, the Society for Maternal Fetal-Medicine, and the America Academy of Pediatrics. We issued a health advisory to help clinicians in recognizing, managing, and reporting Zika and recently held a clinician outreach call that

reached nearly 3,000 participants and more than 150 partner organizations. CDC will continue regular ongoing engagement of clinicians through direct outreach and partnerships with key medical societies

CDC also wants to ensure that the general public knows what they can do to protect themselves. Pregnant women should consider postponing travel to regions with ongoing Zika virus transmission. If they must travel, or if they live in affected areas, CDC recommends pregnant women talk to their doctors or other healthcare providers first and strictly follow steps to prevent mosquito bites. Reducing exposure to mosquitoes is important for anyone traveling to or residing in areas where the virus is circulating by wearing long sleeves, long pants, using EPA-registered repellents such as DEET and permethrin-treated clothing (both of which are safe to use in pregnancy), and using other protections such as air-conditioning to reduce exposure to daytime mosquitoes. For women living in areas with Zika virus outbreaks, CDC appreciates that the timing of pregnancy is a personal and complex decision for a woman to make in consultation with her doctor or other healthcare provider. Efforts to prevent unintended pregnancy, including assisting women and their partners in choosing appropriate and effective methods of birth control, are important conversations for women to have with their healthcare providers, regardless of the presence or absence of Zika virus. Given the potential for Zika virus to be spread through sex, if male partners have or are at risk for Zika virus infection, pregnant women and their male partners should consider abstaining from sexual intercourse or using condoms. This is a rapidly-changing situation and our understanding of the risks concerning Zika virus infection, including those surrounding transmission from mother to fetus and those concerning transmission between sexual partners, is incomplete and evolving. As we get new information, we will update our advice.

Global Activities

CDC is coordinating its response with the Pan-American Health Organization, the regional body of WHO, with other parts of WHO, and is collaborating with many international partners to learn more about this outbreak. We are working with the Brazilian Ministry of Health on research partnerships. Specifically, one partnership will be studying the link between Zika virus infection and microcephaly, while the other is examining the relationship between Zika virus and Guillain-Barré. Research teams from CDC are also in other countries to explore collaborations that will shed light on the risk of microcephaly with maternal Zika virus infection during pregnancy.

In addition, CDC has offered to all countries to test samples from microcephaly cases for serologic evidence of Zika virus infection and to help these countries establish in-country diagnostic capacity. To that end, we are currently providing training to laboratorians in South and Central America on diagnostic tests, including two recent workshops in Brazil and Nicaragua.

CDC's Global Disease Detection (GDD) program rapidly detects, accurately identifies and promptly responds to emerging infectious diseases such as Zika virus. The GDD Operations Center has been monitoring the spread of the epidemic from Brazil to other countries in the Americas since Brazil first reported Zika transmission in May of 2015. CDC's Central American office has facilitated the verification of Zika cases in several countries throughout Latin America, including Colombia, Venezuela, and Nicaragua. The GDD program has also been working to ensure that new information regarding Zika virus and its possible link to birth defects is communicated to U.S. Mission Health Unit staff throughout the Americas.

Research Activities

More research is critical to addressing several gaps in our ability to respond to Zika. We need a better understanding of the epidemiology of Zika and potential Zika-associated birth defects and other adverse

health outcomes. We need better diagnostic methods that can quickly and clearly differentiate between similar viruses to detect evidence of past Zika infection. Currently, a Reverse Transcription-Polymerase Chain Reaction (RT-PCR) test can provide a definitive diagnosis of Zika, but only if it is performed within about a week of symptom onset. The tests we have available for Zika in persons who are no longer ill may have cross-reactivity with similar flaviviruses, particularly dengue, which can lead to false-positive or inconclusive results. Diagnosis is particularly challenging with Zika virus since most people will not experience symptoms and therefore will not go to their healthcare provider in time for PCR-testing to be utilized.

Additional research is also needed to develop methods of mosquito control. Existing methods for mosquito control all have shortcomings, especially in areas where the population of *Aedes* vector mosquitoes is rampant. Vector control is particularly challenging with this specific type of mosquito because of its preference to live in and around houses, the fact that it bites during the day, and its ability to breed in very little water. More work and research is necessary to enhance and improve current vector control strategies and identify better options. Better mosquito surveillance is also vital to determine the location of mosquitoes and areas with mosquito resistance to insecticides which would inform the implementation of new mosquito control techniques.

Finally, a vaccine is needed to protect people at risk of Zika virus infections, particularly women of childbearing age. NIH, in collaboration with ASPR/BARDA, will address the possibility of developing such a vaccine based on vaccines for dengue and West Nile virus that have been in development. NIH also is exploring other vaccine development strategies. At CDC, our scientists developed both a West Nile virus vaccine which is currently in use for animal protection in the United States, and a dengue vaccine, which is currently in clinical trials.

Conclusion

Nature is a formidable adversary. To protect Americans, we need to invest in the laboratories, disease detectives, disease tracking systems, mosquito control, and investigations needed to continue to improve these essential tools. Investment in both the practice and research on new means of mosquito control is particularly important, as is work on a vaccine. As the Nation's health protection agency, CDC is focused on responding quickly to new and emerging health threats such as the Zika virus.

In addition, of the more than $1.8 billion in the President's emergency funding request to prepare for and respond to the Zika virus, $828 million is for activities at CDC. This includes funding to support prevention and response strategies through:

- Supporting Zika virus readiness and response capacity in states and territories with mosquito populations that are known to transmit Zika virus, with a priority focus on areas with ongoing Zika transmission;
- Enhancing mosquito control programs through enhanced laboratory, epidemiology and surveillance capacity in at-risk areas to reduce the opportunities for Zika transmission;
- Establishing rapid response teams to limit potential clusters of Zika virus in the United States;
- Improving laboratory capacity and infrastructure to test for Zika virus and other infectious diseases;
- Implementing surveillance efforts to track Zika virus in communities and in mosquitoes;
- Deploying targeted prevention and education strategies with key populations, including pregnant women, their partners, and health care professionals;
- Expanding the CDC Pregnancy Risk Assessment Monitoring System, improve Guillain-Barré syndrome tracking, and ensure the ability of birth defect registries across the country to detect risks related to Zika;
- Increasing research into the link between Zika virus infections and the birth defect microcephaly and measure changes in incidence rates over time;

- Enhancing international capacity for virus surveillance, expand the Field Epidemiology Training program, laboratory testing, health care provider training, and vector surveillance and control in countries at highest risk of Zika virus outbreaks; and
- Improving diagnostics for Zika virus, including advanced methods to refine tests, and support advanced developments for vector control.

We look forward to working with the Congress on the implementation of the President's emergency funding request.

CDC's current response to the Zika outbreak in the Americas again demonstrates our commitment to global health security and why implementation of the Global Health Security Agenda (GHSA) is needed. Global health security is a shared responsibility that cannot be achieved by a single actor or sector of government.

In partnership with other nations and international organizations, the CDC is committed to mounting a prompt, coordinated response to the emerging threat of Zika virus in order to protect the people both in the United States and around the world.

Thank you again for the opportunity to appear before you today. I appreciate your attention to this concerning outbreak and I look forward to answering your questions.

Mr. SMITH. Dr. Frieden, thank you very much for your testimony. Dr. Fauci.

**STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. FAUCI. Thank you very much, Mr. Chairman, Chairman Duncan, Dr. Bera. It is a pleasure to be with you this afternoon and to discuss with you the research conducted and supported by the National Institutes of Health in addressing the Zika virus situation that we currently find ourselves in.

It is important to point out that we are part of a government-wide and HHS concentrated effort with our sister agencies CDC, FDA, and others within HHS to address the public health issue of Zika. Our role is in the area of basic and clinical biomedical research.

As shown on this slide, the National Institute of Allergy and Infectious Diseases, the institute that I direct, has a dual mandate. And the mandate is to not only, in the classic way, support a robust basic and clinical research portfolio in microbiology infectious diseases, but simultaneously, to be able to respond almost immediately to a new and emerging threat, the situation we find ourselves in right now with Zika.

As I wrote in this article just a few weeks ago in the New England Journal of Medicine, "Zika Virus in the Americas: Yet Another Arbovirus Threat," and the point that I made in this article is that if you look just in the Americas, notwithstanding the rest of the world, over the last few decades, what we have seen was an explosion of not only dengue virus but new viruses that had never before been seen in the Western Hemisphere. Dr. Frieden mentioned a couple of those: West Nile virus, chikungunya virus in the Caribbean, and now Zika virus in the Americas. These are mosquito-borne viruses that have the capability of spreading very rapidly. And what we have been able to do, and I am going to describe a bit of that for you and then, obviously, leave time for questions later, of what the approach of the NIH and NIAID has been.

Our major mandate is to provide the basic understanding of the disease, the clinical research, the resources for researchers throughout the country and the world, as well as biotech companies, with the ultimate goal of developing what we call our countermeasures in the form of diagnostics, therapeutics, and vaccines. So, let's take a very quick look at some of these and how they relate to the situation with Zika.

Dr. Frieden mentioned the issue of epidemiology and natural history. We have our grantees and contractors who have been studying similar diseases like the flavivirus dengue to try and understand what we call the natural history. What is the difference between symptomatic and asymptomatic disease and what is the relationship direct or indirect, alone or synergistic between an infected pregnant woman and the development of congenital abnormalities like microcephaly? What, indeed, is the broad spectrum of the pathogenesis of microcephaly? All of these are questions that we

are asking alone and together with our colleagues, including those at the CDC, to try and get quick answers.

If one looks at the basic science, if you look at other viruses that we have been studying, HIV, influenza, or even Ebola, because of the effort in trying to understand the fundamental molecular virology. We have put an incredible amount of effort and learned an awful lot. We need to do the same thing with Zika virus, studying the viral structure, comparing for example the nature of the virus in outbreaks in the Island of Yap, together with French Polynesia, together with what we are seeing now. Has it evolved? If it has evolved, has it impacted the pathogenesis and manifestations of disease?

In addition, we will be establishing animal models. With any new disease it is important to understand pathogenesis, as well as to screen for drugs and test for vaccines, and animal models are critical to these efforts.

Dr. Frieden mentioned the issue of vector control. There are a number of ways to do that, the classic ways but also some novel ways which we are exploring but should not take the place of the classic ways and that is things like the genetic manipulation of mosquitos or infection of mosquitos with Wolbachia bacteria. Again, I want to emphasize that this is not an easy thing to do, as Dr. Frieden has emphasized. Vector control is a very important tool but it is not easy to implement.

We mentioned diagnostics. The CDC is taking the lead on that, but our grantees and contractors are using some of the knowledge gained from our studies in chikungunya, in dengue, and in other viruses to get more precise state-of-the-art, point-of-care specific diagnosis so we can tell a woman who may not know whether she got infected, whether she actually had been infected with Zika during her pregnancy or before.

Importantly, our role in the development of a vaccine is actually encouraging news. And the reason I say encouraging is because we have had positive experience with the development of vaccines for other flaviviruses. Case in point, dengue, in which there is already an approved vaccine in Brazil and Mexico, and we have started last month a Phase 3 trial of a dengue vaccine candidate in Brazil, in collaboration with the Instituto Butantan.

In addition, for West Nile virus, another flavivirus, we successfully made a vaccine. Unfortunately, even though we went through Phase 1 clinical trials with good safety and immunogenicity data, we could not find a pharmaceutical company that wanted to partner with us because it was felt that this was not something that would have a good profit because of the target population for this vaccine. I don't believe at all that we will be left with this problem with Zika, since we already have a considerable amount of interest on the part of pharmaceutical companies. We are going to use the same technologies that we used to develop the vaccines for other flaviviruses. We are already manufacturing what we call the construct for that, which we will make to the point of GMP, conduct toxicity studies, and get into a Phase 1 trial I would think, and almost be certain, by the middle of this summer, which will be asking for safety and immunogenicity.

This is the schematic diagram of the vaccine that we used for West Nile. It is what is called the DNA construct in which you insert the gene first of West Nile virus. We will substitute the gene of Zika virus, inject it into an individual which would produce now viral-like particles which we know are safe and we know they are immunogenic.

And also therapeutics, although it isn't as high a priority as vaccines, since it is a transient infection and we have to do a lot of screening, we, nonetheless, are looking very carefully with our drug screening capability at possible therapeutics for the entire class of flaviviruses.

I want to close with this last slide, which reminds us of something that I said in the very beginning of my presentation, that microbes have emerged, are emerging, and will continue to emerge. And I refer to it as the perpetual challenge because we know that we are talking about Zika today and next month or next year, we will be talking about something else in the same way as last year we spoke about Ebola. And I know I want to thank the Congress for the support that you have given us over the years to allow us to address these problems.

Thank you very much, Mr. Chairman. I will happy to answer any questions.

[The prepared statement of Dr. Fauci follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

# Research Conducted and Supported by the National Institutes of Health (NIH) in Addressing Zika Virus Disease

Testimony before the

House Committee on Foreign Affairs

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
and Subcommittee on the Western Hemisphere

Anthony S. Fauci, M.D.

Director

National Institute of Allergy and Infectious Diseases

National Institutes of Health

February 10, 2016

Chairman Smith, Chairman Duncan, Ranking Member Bass, Ranking Member Sires, and Members of the Subcommittees:

Thank you for the opportunity to discuss the National Institutes of Health (NIH) research response to Zika virus, an emerging public health threat of international concern. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead institute of the NIH for conducting and supporting research on infectious diseases, including flaviviruses such as Zika virus.

NIAID's mission is research to better understand, treat, and ultimately prevent infectious and immunologic diseases. This is accomplished through a spectrum of research, from basic studies of the mechanisms of disease to applied research focused on developing diagnostics, therapeutics, and vaccines. As part of this mission, NIAID has a dual mandate encompassing research on ongoing health issues as well as the capability to respond rapidly to newly emerging and re-emerging infectious diseases such as Zika virus. NIAID's collaborations with other Federal Agencies such as the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), including the Biomedical Advanced Research and Development Authority (BARDA), and the Food and Drug Administration (FDA), among others, help advance progress against these newly emerging public health threats. In addition, partnerships with academia, the biotechnology and pharmaceutical industries, and international organizations such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO) are integral to these efforts.

The Administration is taking every appropriate measure to protect the American people, and as you know on Monday announced that we are asking the Congress for more than

$1.8 billion in emergency funding to enhance our ongoing efforts to prepare for and respond to the Zika virus, both domestically and internationally, including work on the development of vaccines and diagnostics and to improve scientific understanding of the disease.

## OVERVIEW OF ZIKA VIRUS

Zika virus is a flavivirus. These viruses typically are transmitted predominantly by mosquitoes and often have the ability to spread quickly to new geographic locations because of the widespread prevalence of this vector. Like Zika virus, other well-known flaviviruses including dengue virus and yellow fever virus also are transmitted by *Aedes* species mosquitoes. Zika virus was first discovered in monkeys in Uganda in 1947 and is now endemic to Africa and Southeast Asia. During the past decade it has emerged in other areas of the world, including Oceania, the Caribbean, and Central and South America, where countries, notably Brazil, are currently experiencing unprecedented Zika transmission.

Infections caused by Zika virus are usually asymptomatic. About 20 percent of infected individuals experience clinical symptoms such as fever, rash, joint pain, and conjunctivitis (red eyes). Symptoms of Zika virus infection in humans are typically mild and brief, with very low hospitalization and fatality rates. Recently, however, Zika virus outbreaks have coincided with increases in two serious medical conditions: Guillain-Barré syndrome (GBS), and microcephaly in infants born of mothers who were infected with Zika virus while pregnant. GBS is a rare, acute, immune-mediated peripheral nerve disease that leads to weakness, sometimes paralysis, and infrequently, respiratory failure and death. During a 2013-2014 outbreak of Zika virus in French Polynesia, 42 cases of GBS were detected, well above expected levels.

More recently, the outbreak of Zika virus disease in Brazil has coincided with an increase in the number of infants born with microcephaly, a birth defect characterized by an abnormally small head resulting from an underdeveloped and/or damaged brain. In addition, increases in suspected cases of GBS have been noted in Brazil and other countries in the Americas. Further research is needed to better understand the effect of Zika virus infection on the body, particularly during pregnancy; to investigate the potential relationship between Zika infection and microcephaly, as well as the potential relationship between Zika infection and GBS; and to develop better diagnostics, candidate treatments and vaccines, and novel methods of vector control. Currently, no vaccines or specific therapeutics are available to prevent or treat Zika virus disease. Improved diagnostic tests also are needed because Zika virus infection causes non-specific symptoms and can be difficult to distinguish from other mosquito-borne infections such as dengue, malaria, and chikungunya when conducting antibody screening. Moreover, current antibody screening tests can be falsely positive or inconclusive if the individual was previously infected with related viruses such as dengue, which is prevalent in South America and the Caribbean.

## THE SCOPE OF NIH RESEARCH ON ZIKA VIRUS

NIAID has a longstanding commitment to flavivirus research, including extensive efforts to combat diseases such as dengue, West Nile virus, and yellow fever. This research has informed our understanding of the viral genetics, vector biology, and pathogenesis of flaviviruses and will be critical in efforts to learn more about Zika virus. NIAID has responded to the newly emerging Zika virus disease outbreak by expanding our portfolio of basic research on Zika virus and other flaviviruses. For example, NIAID-supported experts have begun characterizing the

molecular structure of Zika virus to inform drug and vaccine development efforts. Ongoing genetic studies are examining Zika virus strains from outbreaks in 2015, 2013, and the 1940s to understand the differences in host immune response and disease pathogenesis of different strains.

NIAID maintains a program that provides preclinical research resources for the use of scientists worldwide to advance translational research against emerging and re-emerging diseases. These resources are designed to bridge gaps in the product development pipeline and lower the scientific, technical, and financial risks incurred by industry. NIAID flavivirus resources include laboratory screening services for drug compounds and repositories containing viral strains from a variety of vector and human sources. Currently, two human-derived and six mosquito-derived strains of Zika virus are available for distribution through NIAID-supported repositories. In addition, NIAID is focusing new efforts on the development of animal models to better understand the effects of Zika virus in humans, especially during pregnancy. NIAID intends to expand these resources and make their availability widely known to the international scientific community to foster Zika virus research and product development.

In January 2016, NIAID issued a notice to researchers highlighting NIH's interest in supporting research and product development to combat Zika virus. Areas of high priority include basic research to understand viral replication, pathogenesis, and transmission, as well as the biology of the mosquito vectors; potential interactions with co-infections such as dengue and yellow fever viruses; animal models of Zika virus infection; and novel vector control methods. In addition, the notice indicates that NIH will pursue Zika virus research to develop sensitive, specific, and rapid clinical diagnostic tests; drugs against Zika virus and broad spectrum therapeutics against multiple flaviviruses; and effective vaccines and vaccination strategies.

NIAID also is partnering with other NIH institutes, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Dental and Craniofacial Research (NIDCR), to accelerate Zika virus research as it relates to the mother-infant pair. The Institutes are planning to issue a notice that indicates NIH's interest in supporting research to understand transmission, optimal screening and management in pregnancy, and the mechanisms by which Zika virus affects the developing nervous system, including potential links to microcephaly.

## DEVELOPING TOOLS TO COMBAT ZIKA VIRUS

In response to public health concerns about Zika virus, NIAID has accelerated ongoing flavivirus research efforts to speed the development of tools that could help control current and future outbreaks of Zika virus.

### Vector Control

For many years, NIAID has supported extensive research to understand the biology of mosquitoes to help develop tools to limit the spread of deadly mosquito-borne diseases such as dengue and malaria. This research aids in vector control strategies to reduce mosquito bites or limit mosquito populations. In the Americas, Zika virus is transmitted primarily by *Aedes aegypti* mosquitoes, and vector control or other methods to prevent exposure to these mosquitoes are currently the only ways to prevent Zika infection. NIAID plans to support vector competence studies to test various mosquito species for their ability to carry and transmit Zika virus and for insecticide resistance. Understanding the specific mosquito species involved in Zika outbreaks and which insecticides may be effective against them will aid current vector control efforts and may inform novel mosquito control strategies in the future.

## Diagnostics

Accurate diagnostic tests for Zika virus infection are needed to distinguish it from other flavivirus infections and to identify women who have been infected with Zika virus and may be at risk for developing complications during pregnancy. Blood, organ, and tissue donor screening tests are also needed to assure the safety of transfusion and transplantation in areas of active mosquito borne virus infections. Currently, Zika virus itself can often be detected during the acute phase of infection and up to seven days after the onset of symptoms using diagnostic tests for viral RNA (RT-PCR test). While prior infection can be detected by testing for the presence of antibodies against Zika virus, assays for Zika antibodies may also detect or cross-react with antibodies against other flaviviruses, particularly dengue virus. For this reason, a positive antibody test does not definitively confirm prior Zika virus infection in the setting of possible co-infection or prior infection with dengue and other related viruses, and separate confirmatory testing is required. This is a particular concern in South America where there is a high level of exposure to other flaviviruses such as dengue virus.

To facilitate the development of improved Zika virus diagnostic tests, NIAID grantees are working to generate antibodies that can distinguish between Zika virus and dengue virus. They also are working to identify biosignatures unique to Zika infection that could form the basis of additional rapid, specific, and sensitive diagnostic tests. In addition, NIAID is pursuing the development of a mouse model of Zika virus infection that could be used to test new diagnostic tools.

## Vaccines

A safe and effective Zika vaccine would be a critically important tool to stop the spread of infection and prevent future outbreaks. NIAID is investigating multiple Zika virus vaccine

candidates, including vaccines based on technologies that have shown promise in targeting other flaviviruses. The NIAID Vaccine Research Center is pursuing a DNA-based vaccine for Zika virus that is similar to the West Nile virus vaccine previously developed by NIAID. In Phase 1 testing, this West Nile vaccine candidate was shown to be safe and generated a strong immune response in humans, offering a model for Zika vaccine development. NIAID scientists also are designing a live, attenuated vaccine, building on a similar approach used for the closely related dengue virus. That dengue vaccine candidate showed an excellent safety profile and generated strong immune responses in early-phase clinical trials; in January, a large Phase 3 dengue vaccine trial was launched in Brazil in collaboration with the Butantan Institute. Finally, NIAID grantees are in the early stages of developing a Zika virus vaccine based on a recombinant vesicular stomatitis virus – the same animal virus used successfully to create an investigational Ebola vaccine candidate – that expresses the Zika E glycoprotein. Plans are underway to evaluate this potential vaccine construct in tissue culture and animal models. While these approaches are promising, it is important to realize that the development of investigational vaccines to establish whether they are safe and effective takes time. Although a safe and effective, fully licensed Zika vaccine will likely not be available for a few years, we hope to begin early-stage clinical testing of one or more NIAID-supported vaccine candidates in 2016.

**Therapeutics**

NIAID has an active program to screen for antiviral drugs active against viruses in the flavivirus family, including dengue, West Nile, yellow fever, Japanese encephalitis, and hepatitis C viruses. NIAID has enhanced these efforts with the recent development of an assay to test compounds for antiviral activity against Zika virus. NIAID will make this test available to the research community and will soon test 10 antiviral compounds with activity against other

flaviviruses to determine if they are effective against Zika virus. Promising drug candidates identified by the assay could be further tested in a small animal model of Zika virus infection developed with NIAID support. The ultimate goal of NIAID-supported flavivirus therapeutic research is to develop a broad-spectrum antiviral drug that could be used against a variety of flaviviruses, including Zika.

**Emergency Request for Vaccine Research and Diagnostic Development and Procurement**

As I noted in the introduction to my testimony, the Administration has announced an emergency-funding request of more than $1.8 billion to combat the Zika virus both domestically and internationally. Included in the request are resources for Zika-related vaccine research, rapid advanced development, and commercialization of new vaccines and diagnostic tests for Zika virus. The funding will allow NIH to build upon existing resources and work to develop a vaccine for Zika virus and the chikungunya virus, which is spread by the same type of mosquito. Funding will accelerate this work and improve scientific understanding of the disease to inform the development of additional tools to combat it. The request also includes resources for FDA to support Zika virus medical-product development, including the next-generation diagnostic devices. We look forward to working with the Congress to implement this request.

## COLLABORATIONS

Investigation of emerging and re-emerging infectious diseases requires expertise from a variety of fields. In the case of Zika virus, studies of virology, immunology, natural history, neurology, and neonatology will be required to fully understand the pathogenesis of this infection. As mentioned previously, NIAID is partnering with other NIH institutes including NICHD and NINDS to better understand the potential association between Zika virus infection

and neonatal defects. In addition, NIAID will partner with NINDS to investigate microcephaly linked to Zika virus infection and how these cases may differ from microcephaly caused by other infections.

NIAID also is employing partnerships with research institutions in South America to advance research on Zika virus infection; additional collaborations with academic, industry, and government partners are under active exploration. NIAID held a joint meeting in December 2015 with Brazilian research institute Fiocruz in which Zika was a key area of concentration. In addition, NIAID is collaborating with other HHS agencies in responding to the Zika epidemic. For example, NIAID, CDC, BARDA, ASPR, and FDA are jointly convening a Zika virus workshop on March 28-29, 2016, where the latest information on Zika virus will be discussed by experts from Federal Agencies, academia, and pharmaceutical and biotechnology companies. Topics to be addressed at the workshop include virology, epidemiology, possible links to microcephaly, and efforts to develop diagnostics, therapeutics, and vaccines.

## CONCLUSION

NIH is committed to continued collaboration with HHS agencies and other partners across the U.S. Government in advancing research to address Zika virus infection, and we look forward to working with the Congress to implement the President's emergency funding request. As part of its mission to respond rapidly to emerging and re-emerging infectious diseases throughout the world, NIAID is expanding our efforts to elucidate the biology of Zika virus and employ this knowledge to develop needed tools to diagnose, treat, and prevent disease caused by this virus. As Agencies of the U.S. Government work together to address this new public-health concern, NIH will move quickly to conduct and support research to combat Zika virus and

inform the global public health response in partnership with the affected communities and academic and industry researchers worldwide.

Mr. SMITH. Dr. Fauci, thank you very much for your testimony. Without objection, all of your full statements, which are very lengthy and detailed will be made a part of the record.

I would like to now go to Dr. Pablos-Mendez.

**STATEMENT OF THE HONORABLE ARIEL PABLOS–MENDEZ, M.D., ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT**

Dr. PABLOS-MENDEZ. Thank you, Chairman Smith, Chairman Duncan, Ranking Member Sires, and Dr. Bera and all the distinguished members of the subcommittees for inviting me here today to testify on the United States Agency for International Development, USAID's response to the serious concerns raised by the spreading in the Americas of the Zika virus.

And I want to recognize the leadership of my colleagues, Dr. Frieden and Dr. Fauci that have been rapidly mobilized in the response and the immediate investigation that we already are learning a lot. But as we have learned from other outbreaks, we cannot wait to figure it all out before we begin to have this discussion and a response.

And on Monday, the President submitted a Fiscal Year 2016 supplemental request to aggressively respond to the Zika virus outbreak. The supplemental request includes $335 million for programs to be implemented by USAID so that we can help countries in the region affected by Zika respond and protect their citizens and, in doing so, attenuate its spread to our homeland.

Let me briefly describe the components of the work that we propose for implementation by USAID. First, we will support brisk communications and behavior change programs. As Dr. Bera recognized, getting the right information to the people, empowering people with the right information, and this is going to be a rapidly evolving field, we don't want panic to take place in the region as we actually take actions to help protect themselves from the Zika, as well as other mosquito-borne diseases. This includes mobilizing communities on vector control, providing clear information for women concerning the risk of the Zika virus and pregnancy, and how to protect themselves. Community level messaging will be combined with mass media and social media campaigns. We will also partner with the private sector and I am in discussions with companies in Brazil at this moment to help us do that.

Secondly, USAID will support implementation of a package of integrated vector management, vector control activities in communities at risk of Zika. This will help reduce exposure to mosquitos and will help protect against other vector-borne diseases such as dengue, as we heard just now.

Specific activities will include community mobilization campaigns to reduce or eliminate standing water sources where Aedes aegypti mosquitos breed, focal larviciding based on vector mapping to eliminate major breeding sites and window-endorsed screening to reduce mosquito entry to homes, schools, hospitals, and workplaces.

The approaches we have today to reduce Aedes aegypti mosquito are not optimal. They have been shown to work in a number of settings and we certainly are going to be working with our partners in developing new tools and as they do, we want to make sure they

become available rapidly in the region. These efforts were built upon the foundation of experience of the successful President's Malaria Initiative, aware that the Zika virus is carried by a different mosquito. We have expertise in mapping, expertise in entomology, and so that can be brought to bear also in the response to Zika.

Thirdly, USAID will help ensure that women in affected countries have access to appropriate healthcare and support. This will include training of healthcare workers to provide advice, providing support for pregnant women, including helping them access repellant to protect against mosquitos and ensuring access to voluntary family planning, as we heard from Mr. Duncan. These will be important to have information, to have services, to have community, to have methods, as well as the care of the affected newborns. And I know that Chairman Smith has always had a concern for the newborn.

Finally, innovation. We can take steps to spur development of new tools and other innovations to enhance our response and prevent future outbreaks. And the baseline of research that NIH leads is significant. Our partners at NIH and CDC are supporting this critical research already and we need to better understand the virus and the relationship with birth defects, and developing new tools.

As we have learned, the markets need to be incentivized, need to be organized and market incentives can be of significant importance to help us bring those tools to fruition and to quickly deploy them in the region.

Market incentives can be used throughout the development process from catalyzing early stage development of diagnostics, therapeutics and vaccines, and as well to incentivize most costly, late-stage product development manufacturing and scale.

In response to the Ebola epidemic, USAID used grant challenges to rapidly source new innovations to address key gaps in a response and we are planning also considering new grant challenges to bring new ideas to bring to private sector in diagnostics, vector control, personal control, and the like.

Mr. Chairman, Zika, like MERS, SARS, avian influenza, and Ebola all point to a landscape where the interaction between humans, animals, vectors is constantly changing. In our civilization, for the first time, we are seeing an explosion in the tropical regions of the world of the forestation and increase in need demand as economic development takes place, urbanization changes, and global travel and the like. Ecological transformation and climate, weather patterns change are increasingly interconnected in our world and that means that mosquito-borne diseases, such as Zika, can appear in areas they haven't before. These rapidly changing dynamics means that we have to be prepared for what is seemingly unpredictable and when we have a response, we seem to be as outsmarted by these viruses.

A recent report from the National Academy of Medicine on Global Health Risk Framework estimates the annualized cost of pandemic risk is about $60 billion a year and there are other estimates that are actually higher than that. So, we need to make sure that we are prepared because both the cost in life and the cost to the economy is likely to grow in coming decades.

As we address the immediate needs of the Zika-affected population, we must underscore the need to improve national systems to prevent, detect and respond to these pathogens and I think this is the effort at the heart of the Global Health Security Agenda launched in early 2014.

Beyond dealing with individual outbreaks, and we are seeing, as Dr. Fauci put it, a perpetual challenge, one coming after the other, we need to also pay attention to the landscape where they are coming, better understand the territory where they are coming. USAID, for a number of years, has supported work that builds capacities and expands the evidence base, that helps predict and mitigate the impact of novel high consequence pathogens. And we, every year, we are detecting hundreds of these new pathogens. We are screening them. We are ensuring that they don't jump into the human space. We find them in primates. We find them in birds. We find them in bats. We find them in rodents but it is not an infinite landscape. There is a logic to it and we want to make sure science is brought to bear to address, indeed and prepare and predict these challenges.

We must keep this bigger picture and the long-term view if we are to prevail against this rapidly evolving what I call the microbiome of the world.

In conclusion, Mr. Chairman, USAID is strongly committed to combating the Zika virus outbreak of today and is strengthening the capacities to ensure that future threats will be rapidly and effectively controlled at their source and before they pose a threat to the global community. We look to your partnership and your leadership as we continue this fight.

I appreciate the opportunity to share the contributions that we are making in this battle. Thank you very much.

[The prepared statement of Dr. Pablos-Mendez follows:]

**Ariel Pablos-Mendez, MD, MPH**
**Assistant Administrator for Global Health**
**U.S. Agency for International Development**

**Joint hearing before the**
**House Committee on Foreign Affairs**
**Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations and the**
**Subcommittee on the Western Hemisphere**

**February 10, 2016**

Thank you Chairman Smith, Chairman Duncan, Ranking Member Bass, Ranking Member Sires and distinguished members of the Subcommittees for inviting me here today to testify on the response of the U.S. Agency for International Development (USAID) to the Zika virus outbreak. I want to thank you for your continued leadership and commitment to global health and global development issues. We see you as partners in USAID's mission to end extreme poverty, and promote resilient, democratic societies while advancing our security and prosperity.

On Monday, the President announced his intent to submit a Fiscal Year 2016 supplemental request to aggressively respond to the Zika virus outbreak. USAID is included in this request so that we can help countries affected by the Zika virus respond and protect their citizens. In my testimony today, I will describe what USAID is prepared to do with existing and supplemental resources to respond as part of an interagency effort, discuss Zika within the context of the challenges of infectious diseases and the, and share what we and other partners are doing to help countries around the world prevent, detect and respond to infectious diseases.

**A serious concern**

On February 1, the World Health Organization announced that the recent cluster of microcephaly and other neurological disorders reported in the Americas constitutes a Public Health Emergency of International Concern. There is a temporal association between this cluster and Zika virus disease outbreaks in this region. This cluster of microcephaly cases is not only devastating for the affected children and their families but it also raises many questions for pregnant women and their families across the Americas.

Zika was first identified in Uganda in 1947, and has been found to cause illness in Africa and Asia, before the recent outbreaks in Latin America. But, our knowledge of the virus and its relationship to the microcephaly cases has many gaps and studies are underway to better understand the morbidities caused by the virus.

However, it is important to recognize that national surveillance systems, laboratory capacity, and preparedness across the developing world are insufficient to deal with the influx of new and emerging pathogens. It is estimated that of the 194 countries committed to International Health Regulations, only 35 percent are fully prepared to detect and respond to pandemic threats.

USAID, working with our interagency and international partners is working to address this through many of our existing programs. In addition, there are also tools, albeit limited, at our disposal to slow the transmission of Zika virus by the *Aedes Aegypti* mosquito. Vector control of adult *Aedes aegypti* is difficult to do correctly and is labor- and cost-intensive. We need new tools and enhanced capacity.

**Proposed activities**

Today you will hear from my colleagues at the Centers for Disease Control and Prevention as well as the National Institutes of Health, about their efforts to develop new tools and diagnostics to address this virus. USAID is uniquely positioned to take these new tools and techniques and apply them to the Zika virus outbreak. The FY 2016 supplemental request for the Zika virus includes $335 million for programs to be implemented by USAID. Building on lessons learned from Ebola, USAID will roll out communication/behavior change campaigns in association with our CDC, WHO/PAHO and local partners; support community implementation of integrated vector management strategies; help ensure that women in affected countries have access to appropriate health care and support and the best information available – recognizing that the best information is indeed changing quickly; and in collaboration with our CDC and NIH and other research colleagues, use some of the approaches USAID has in place to leverage the private sector and speed the development and introduction of innovations to address Zika and other infectious diseases.

Due to USAID's long-standing relationships with national governments, international organizations, non-governmental organizations and the private sector, we will look to find ways to build on each country's existing maternal and child health, reproductive health, and HIV/AIDS platforms to respond to this virus. We are prepared to begin our efforts in the Americas and expand into other regions as needed.

Following are the specific components of the FY 2016 supplemental request for USAID:

Communication/Behavior Change Strategy:

There are immediate needs and opportunities for clear and important messaging about the virus. The content of the messaging will be iterative and will reflect new information as it becomes available. Empowering communities to take actions to protect themselves is key to protecting communities from the Zika virus as well as other mosquito-borne diseases. As our recent experience in West Africa during the Ebola outbreak has shown, even in the absence of readily available medical countermeasures, providing communities with actionable information results in reduced infection rates and incidence. Key to successful community action is involving community voices so that together solutions are developed and executed.

For example, communications messaging can reinforce national vector control operations that target the mosquitoes that are spreading the virus. Successful control of the mosquitoes, and ultimately the spread of the virus, is very much dependent on communities adopting local environmental control measures to reduce the mosquito populations, such as reducing standing water in tires or other receptacles, and assessing the local environment to determine where the

mosquitoes are most likely to breed – and eliminating those breeding sites. It is important to note that the measures being proposed to respond to the Zika virus will also prove to be equally effective against diseases, such as dengue and chikungunya, that are spread by the same mosquito species.

In addition, we will couple community level messaging with comprehensive mass media and social media messaging campaigns that will include partnerships with communications firms and large corporations, particularly in Latin America. We will build on messaging best practices that were learned in West Africa and will seek to leverage funding as much as possible from other donors and the private sector. For example, in West Africa during the Ebola outbreak, USAID; partnered with BBC Media Action and the Paul Allen Foundation to implement a large-scale effort to educate the public on how to mitigate the risks of Ebola. This proved highly effective, and the technical inputs were provided by USAID while most of the operational costs were borne by our private sector partners.

Community Implementation of Integrated Vector Management:

USAID will support implementation of a package of integrated vector management activities in communities at risk of the Zika virus to mitigate mosquito exposure. These activities could include robust community mobilization campaigns tailored to each community to actively reduce/eliminate standing water sources where *Aedes Aegypti* mosquitos breed, focal larviciding based on vector mapping and resistance data to eliminate major breeding sites, and window and door screening to reduce mosquito entry into homes and other important community settings such as schools, hospitals and workplaces. This effort will complement the communication/behavior change campaign and be integrated into community mobilization activities to reinforce personal protection measures, such as appropriate clothing to reduce skin exposure, repellents, etc. All of this work would follow standard environmental safeguards. These integrated vector management efforts will also incorporate new vector control tools as they become available including insecticide-based products and interventions deemed effective against *Aedes Aegypti* mosquitos. These efforts will build upon the foundation of experience and learning under the successful President's Malaria Initiative vector control programs in Africa, while also tailoring the interventions to the specific breeding patterns and feeding behaviors of *Aedes* mosquitos, which of course are different than the malaria-transmitting *Anopheles* mosquito.

Maternal Health Care:

Health care workers are a direct link to the community and in many situations the "first responder" when a health event occurs. USAID has extensive partnerships and platforms to strengthen the capacity of health care workers to provide clear counseling and care to at risk or affected families. Building on USAID and the USG's existing PEPFAR, maternal and child health, and family planning platforms, we will expand access to care and support for impacted women and their families. As we have seen with dengue, good patient care is a critical component of an effective and comprehensive program. This includes support for training of health care workers, and updating the information and training as new data becomes available; providing support for pregnant women, including helping them access repellant to protect against

mosquitos; ensuring access to voluntary family planning information, services, and methods; and providing information about microcephaly and best practices for supporting children with microcephaly.

Innovations:

My colleagues from NIH and CDC have described the critically important research they are currently supporting to address the Zika virus and other vector borne diseases. They will be working diligently to develop the urgently needed tools and understand the relationship between the Zika virus and birth defects. As we have seen in other areas, use of market incentives can also speed the development of these new tools and help get them quickly into use.

For example, market incentives can be used throughout the development process, from catalyzing early-stage development of diagnostics, therapeutics and vaccines or other tools, to incentivizing more costly late-stage product development, manufacturing and scale. Product development partnerships such as FIND – the Foundation for Innovative New Diagnostics – have been successful in partnering with the biopharmaceutical companies to accelerate the development of global health innovations. For example, FIND has partnered with small biotechnology firms to push the development of critically needed diagnostics for neglected diseases, including the Xpert MTB/RTF drug-resistant tuberculosis diagnostic tool. Multi-donor partnerships such as Gavi have played a critical role incentivizing development and manufacturing of late-stage vaccines. Gavi recently announced a small advance purchase commitment of an Ebola vaccine to pull the late stage vaccine toward licensure. USAID has been a proud supporter of Gavi and collaborated closely with FIND. These kinds of approaches could be very valuable for pushing forward innovations for detecting, preventing and treating Zika virus.

USAID has also had tremendous success with its Grand Challenges for Development initiative, sourcing groundbreaking innovations from all over the world. USAID is prepared to build on the successes of the Grand Challenge undertaken during the Ebola epidemic where we rapidly sourced new innovations to address key gaps in our response. Areas of focus of a new Grand Challenge could include innovative solutions to address critical shortcomings in diagnostics, vector control, personal protection and community engagement.

The Ebola Grand Challenge demonstrated that it is possible to rapidly source new innovations during an outbreak. The Challenge generated over 1,500 ideas within weeks of launching and USAID – in close partnership with the White House Office of Science and Technology Policy, CDC and the Department of Defense – selected 14 promising innovations across five areas including:

- Healthcare Worker Safety: Re-engineered protective suits and improved methods of decontamination.
- Cutting-Edge Health Care Worker Tools: A wearable, Bluetooth-enabled patient sensor to track key patient vitals remotely.
- Rapidly Deployable Ebola Treatment Centers (ETCs): Modular ETCs that can be deployed and stood up in days.

- Behavior Change: Song contest in Guinea with top West African musicians.
- Health Information Technology: Open-source mobile platform for health data collection, decision support, patient tracking and an integrated health management system that supports contact tracing and clinical case management.

Several of these innovations are already in use now; others are in testing and are close to approval. For example, CommCare and mHero is used to support contact tracing, health care worker decision support tools, and two-way communication between health care workers and government officials for real-time information sharing. Another example is Drip Assist, a low-cost, battery-powered infusion monitor that delivers fluids with precision to patients, eliminating the risk of fluid overload and enhancing survival. This device received FDA approval last fall and is beginning to roll out. We also supported user testing in Sierra Leone where it was viewed as a real game-changer for healthcare workers who struggle to ensure that their patients get the fluids they need with current tools. The Ebola Grand Challenge also reminded us, however, that while we can source new innovations quickly, research and development can be a lengthy process – particularly in health where safety is paramount. We will look to ensure that any investments we make for the latest outbreak also help to ensure that we are equipped with the most cutting-edge tools to respond to and, ideally prevent, outbreaks of tomorrow.

**Zika, the changing ecological landscape, and the Global Health Security Agenda**

Zika, like MERS, SARS, avian influenza, and Ebola all point to a changing landscape where the interaction between humans, animals, and vectors is vastly different and constantly changing. Ecological and climate change in an increasingly interconnected world mean that mosquito borne diseases such as Zika can appear in areas they hadn't been before. These rapidly changing dynamics are fundamentally altering the emergence patterns of zoonotic and vector borne diseases, and increase the likelihood of new spillover and amplification opportunities for these pathogens into human populations.

In February 2014, the U.S. joined with other countries to launch the Global Health Security Agenda (GHSA). GHSA is an international effort to build capacity to prevent, detect and respond to infectious diseases, and to build political commitment to ensure appropriate action is taken when needed.

As we address the immediate needs of the Zika-affected populations and respond to the potential further spread of the virus, we must take this opportunity to further illuminate the need for improved national systems to prevent, detect, and respond to high consequence pathogens. This effort is at the heart of the GHSA.

If there is anything that Zika has already taught us, it is that there will be a next time – another pathogen that spills into humans with the potential to amplify and spread beyond borders. Our short-term investments in response to and recovery from the Zika virus must be balanced with an outlook for preparing and equipping those countries already committed to the International Health Regulations and Global Health Security Agenda with national preparedness platforms, improved surveillance systems, sustainable diagnostic capabilities, and flexible multi-sectoral response plans.

USAID is one of a number of U.S. government agencies deeply committed to helping achieve the objectives of GHSA. We are working in very close partnership with the White House and our colleagues at the Department of Health and Human Services, including CDC and NIH; the State Department; the Department of Defense, U.S. Department of Agriculture among others. Through GHSA, USAID builds on the significant investments we have made over the past 10 years.

Our work on building zoonotic disease capacity – or "One Health" recognizes the close connection between animal and human health. This work focuses on building those capacities and expanding the evidence base that contribute to mitigating the impact of novel "high consequence pathogens" arising from animals – the primary reservoir for most emerging disease threats.

Overall, USAID's strategic approach to "One Health" has been guided by the following principles:

- All populations are vulnerable to new diseases emerging in other countries; it is in our collective interest to strengthen the capacity of all high-risk countries to prevent the emergence and spread of these new disease threats.
- Deadly zoonotic disease threats, and outbreaks of diseases will increase steadily in the coming decades driven by population growth and expanded interactions between people, animals and the environment.
- Measures are currently available that if properly deployed could greatly reduce the risk of new disease emergence and their impact.
- It is possible, in the event of new disease emergence, to minimize its potential economic and public health impact through enhanced surveillance and early deployment of control measures.
- Enhanced coordination across animal, human, and environmental sectors will contribute to reduced risk of new disease emergence and lead to early and effective control minimizing their impact should they emerge.

At the country level, we work with governments and other key in-country, regional and international partners to characterize the key drivers of disease emergence—from deforestation and land use change to wildlife trade and livestock product demands. This information, along with other investments to strengthen country-level capacities for routine infectious disease detection and outbreak response, have been used to improve surveillance and response as well as to develop risk-mitigation strategies. This work has significantly refined our understanding of the "drivers" that underlie disease emergence and established important new partnerships and platforms for even more timely and effective prevention, detection, and control of future threats. The program draws from across the private sector, universities and non-governmental organizations, as well as UN technical agencies.

GHSA as a global partnership is focused on accelerating progress toward making the world safe from the threats posed by emerging infectious diseases. GHSA recognizes emerging infectious diseases are among the foremost dangers to human health and global security. In January, this

concept was underscored by the National Academy of Medicine when they released, "*The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*." The authors make the point that we will continue to see outbreaks of infectious diseases, and investing in the appropriate preparedness and response capacity should be a core component of global security, and that the annualized cost of pandemic risk is $60 billion. The ongoing outbreak of the Zika virus in the Americas once again highlights our need to collectively invest in maternal child health, disease specific interventions and the Global Health Security Agenda.

**Conclusion**

USAID is committed to addressing the Zika virus outbreak of today and strengthening capacities to ensure that future threats will be rapidly and effectively controlled at their source and before they pose a threat to the global community. Thank you for the opportunity to speak with you today and to share the contributions we are prepared to make. I am happy to answer any questions.

Mr. SMITH. Dr. Pablos-Mendez, thank you very much.

The committees will be following the 5-minute rule for member questioning. I would like to begin and I will just throw out some questions, and then yield to my good friends and colleagues.

First, on vector control capacity, in Africa it took years to build up that capability, especially with the malaria efforts. I know that being safe and effective is important so that we don't have, obviously, unintended consequences from unsafe pesticides, for example. I know, personally, we use, my wife and I, diatomaceous earth at home for certain bugs and insects. Pyrethrum is obviously another possibility. But the question would arise, what are you suggesting that they use? Is there an adequate supply in these countries and an adequate delivery mode?

Secondly, on Brazil, it seems that the areas of the highest prevalence is in areas of extreme poverty. And I know because we work on stunting and other issues in this subcommittee all the time, as a matter of fact, the first 1,000 days of life, in my opinion, is one of the most transformative efforts where nutrition, micro-nutrients, and other kinds of assistance efforts increases the immunity on the part of the baby. It also makes the mom healthier. So, from conception to the second birthday, those first 1,000 days are absolutely transformative. Are you looking into vulnerabilities based on weak or compromised immune systems? And certainly children living where there is extreme poverty and lack of nutrition are likely to have that problem.

Third, on mother-to-child transmission, is that something that you will be looking to develop a way like you, the pharmaceuticals and others did so effectively with regards to mother-to-child transmission with HIV/AIDS?

And then finally, in the United States landmark civil rights legislation, the Americans with Disabilities Act ensures that persons with disabilities are fully enfranchised into society. Dr. Pablos-Mendez, you mentioned in your testimony, looking to encourage other countries to adopt best practices for supporting children with microcephaly, you might want to explain what that will look like in terms of helping those countries care for children with disabilities.

Dr. FRIEDEN. Maybe I can start with your first couple of questions.

On vector control, our approach is to reduce mosquito populations by an integrated comprehensive approach. That means reducing standing water, using larvicides, and there are various forms of larvicides.

We have looked at outdoor spraying and many countries use outdoor spraying. Because the vector bites indoors and because of some other characteristics, there may be limited effectiveness of outdoor spraying.

And one approach that has been used in some places is targeted indoor residual spraying. It is a different type of spraying than spraying done with malaria, different areas of the house, but there may be efficacy there. That is a labor-intensive and complex area.

And underlying all four of those critical approaches is rigorous surveillance for where the mosquitos are and which insecticides

they may be resistant to. And we have those studies underway now in Puerto Rico. We don't yet know what the resistance levels are.

In terms of nutritional or other cofactors and the impact of poverty, that is exactly one of the things that we will be studying in the case control study. There is a lot that we don't know. If there is a causal association, we don't yet know which trimester of pregnancy is the highest risk and, within that, whether it is all pregnancies or a small proportion of them that is affected. And if it is fewer, what might be the risk or protective factors? That is a critical thing that we are investigating now.

Dr. FAUCI. Thank you, Mr. Chairman, let me just address the question of mother-to-child transmission, which is really important. The major difference between mother-to-child transmission and the advances that we have made with HIV/AIDS and the particular challenge of Zika infection in the mother and the transmission to the baby is the chronic nature of the viremia in HIV in which you could suppress the virus in the mother by treating the mother. And we know for certain, by many good studies, that when you bring the level of HIV viremia in the mother to below detectable level, you dramatically decrease the likelihood that the mother will transmit HIV to the baby because you have a lot of time because it is a chronic infection.

When you are dealing with an infection like Zika, which is a flash infection, it comes, it lasts a few days, and then it is gone in the person who gets infected, the way to prevent mother-to-child transmission is exactly what we did with the rubella model. You recall that in the 1960s there were 20,000 cases of congenital rubella syndrome annually in the United States. That is astounding, 20,000 cases, leading to blindness, deafness, heart disease, mental retardation, and other types of congenital abnormalities. If you look at the curve of the epidemiology, when we instituted the rubella vaccine, we essentially targeted everyone—it was specifically targeted to women of child-bearing age because rubella is a relatively mild disease very similar to Zika.

In answer to your question about mother-to-child transmission, the best way to prevent that is to get an effective vaccine and make sure that in the target countries, women of child-bearing age are protected by a vaccine.

Dr. PABLOS-MENDEZ. Mr. Chairman, I would like to address two of your points, one on nutrition and the other on children with microcephaly and disabilities.

We fully agree. Just yesterday we having a review of our nutrition portfolio and the first 1,000 days had been the way in which our work has been best framed to have the most impact but also we drew on the parallels to the current situation with Zika. Those first 1,000 days needs to be crucial, crucial both to the prevention because as you said, malnutrition will expose you to severe infection and then that is the complications that we may be seeing.

Also, malnutrition could play a role itself in leading to under nutrition in utero and even associations of certain deficiencies with complications and deformations and the like.

But the experience and the work that we have in nutrition around the first 1,000 days also bring to bear anthropometrics. The measurement of the heads, for example, is something we need to

do better. We need to have surveillance and reporting system that allows us to do that and the experience and the community centers that we have working in nutrition can be mobilized in this regard.

As you know, we have been very successful with child survival. One hundred million children's lives have been saved in the last 20 years. And in a way, we are looking to the end of preventable child and maternal death and, as we do that, we move from survival to well-being. And the more we do that, we pay attention, indeed, to many of the factors from nutrition education that we have to do, disabilities very important. And the U.S. Government leadership in that space for Americans but also in the U.N. there has been awakening of the importance of paying attention to support for children with disabilities.

The experience we have built on HIV and more recently on Ebola, in terms of those who are affected, in terms of education on the stigma, medical care, and research, as to what will be the spectrum of the impact of these phenomenon we are working on today, and social work to support those families. There is a lot of needs.

We do have, as you know a Center for Children in Adversity at USAID that has been working in this area. So, we look forward to continue to work with you. And we have all of these to mobilize in a region that we have in a way not been as present because of the success in development in this region. We have moved most of our resources to Africa and Asia, where we had the most deaths maternal child health, as well as AIDS, malaria, and tuberculosis.

Mr. SMITH. Thank you.

Dr. Bera.

Mr. BERA. Thank you, Mr. Chairman. And I will try to keep my remarks tight because I know we just we got votes called and we have got a number of members.

I think Dr. Frieden pointed out the difficulty of vector control with this particular mosquito, obviously, that is one of our primary tools but, again, not as easy as with certain other types of mosquitos.

Dr. Fauci, you touched on the importance of developing a vaccine and perhaps the rapidity of developing that vaccine. I would be curious, you were pretty optimistic that we might be able to develop something fairly quickly.

Dr. FAUCI. Let me explain that so that it is clear. In general, vaccines take anywhere from 3 to 8 years to get all the I's dots and the T's crossed, full FDA approval by proving safety and efficacy.

When you are dealing with a situation like this, we have the advantage that we already have the construct that you need, the candidate vaccine platform. If you look at the timetable, you always know that in vaccinology you have to be careful that timetables can slip. But we feel confident that we will have enough construct to be able to do preclinical toxicity studies by this summer, which means we could start a Phase 1 trial, let's say in August. They usually take 3 to 4 months, which means we could be finished by the end of 2016.

Now, the critical issue. If it is safe and immunogenic and the outbreak is still raging, then you could go into an accelerated Phase 2A/2B trial, which means that you could likely determine if it is effective within 6 to 8 months. And if it is, you can get an acceler-

ated approval from the regulatory bodies. However, if when we get to 2017, all of the cases go down, which is what we faced with Ebola. We had an Ebola vaccine and then all of a sudden, the cases disappeared and it was difficult to definitively prove. If it goes down, then you stretch it into several years. But if I am talking to you in February 2017 and we still have a massive outbreak in South America, we likely could prove safety and efficacy within 6 to 8 months.

Mr. BERA. Now, are we going to run into, in terms of commercialization of that vaccine and wrapping up that vaccine, you know working with the private sector to get that vaccine commercialized and distributed, will that be a problem?

Dr. FAUCI. I do not think so, Dr. Bera. And the reason I do not think so is because we are already, unlike the case with other emerging infections, receiving calls from pharmaceutical companies, big pharmaceutical companies very interested in partnering with us. I don't think we are going to have that problem.

Mr. BERA. Great. And again, all three of you touched on the importance of funding global health, the importance of funding global disease surveillance. You know this is just another case of the interconnected world. Disease is going to travel a lot faster and so forth. And I would just put out there the importance of funding and making those funds available and working together.

This is, again, just, you know we had Ebola last year. We have got Zika virus today. We will have another infection next year and again, I would emphasize the importance of this funding.

So, Mr. Chairman, I will go ahead and yield back.

Mr. SMITH. We have a series of votes. I am not sure what your availability is to stay. We could be back in about 15 or 20 minutes. Would that be okay? I deeply appreciate it.

We stand in brief recess.

[Recess.]

Mr. SMITH. The subcommittees will reconvene. And as soon as my colleagues who come, since I have already had my turn, I will yield to them.

But I did ask the question earlier and maybe if you could just elaborate a bit on it and that is the capacity, the actual volume of potential pesticides. I know Dr. Frieden, you talked about the utter importance of draining sitting water. And I know even in the Big Island in Hawaii, there is just a new emergency call because of dengue to go after spare tires that are housing water and then becoming breeding grounds for mosquitos. I get that. That is labor intensive but doesn't require chemicals, per se. What are the actual pesticides that are considered safe and what is the potential supply of those?

Dr. FRIEDEN. Thank you very much. I am glad you came back to that because I wasn't able to address some of the really critical issues there in my earlier reply.

The U.S. capacity for mosquito control is quite variable. So, some parts of the U.S. do this extremely well, some parts not so well. And one of the critical components of the supplemental request is to strengthen mosquito control in the parts of the U.S. that have mosquitos that could spread the Zika virus. And here, we look at a comprehensive approach.

So, on the one hand there are things that you can do to reduce larval populations and their use of what is called BTI or Bacillus and the sphaericus, two different bacteria that actually infect and kill the larval mosquitos are very effective and are used pretty widely in not just human health but agriculture and other areas. There are various other ways of reducing mosquito larva populations but that is one of them.

For the adult mosquitos, there are three broad classes of insecticide and then within those there are many different types of insecticides. Not all of them are licensed for use in the U.S. and we are looking very carefully at what has been done in other countries, including Australia with targeted, indoor residual spraying of insecticides and seeing what would be safe and effective here. So, that is something that we are in frequent discussions with industry partners, as well as EPA and other entities. But there are issues of what we could do that is safe and effective.

The mosquito control efforts are also more than just chemicals. It is about having a surveillance system. So, CDC has invented a type of trap which is currently in use in California and elsewhere that can monitor what the mosquito populations are. CDC laboratories have developed a simple way of testing for insecticide resistance so that we can get a better sense of which should be used because we are seeing reports of insecticide resistance and then looking at where the mosquitos are and what insecticides they are susceptible to, we would then proceed with recommendations for mosquito control. But this is all quite labor-intensive. It needs to be done in the same way you need a public health system to find, stop, and prevent problems, we need a vector control or a mosquito control system to track where the mosquitos are and then respond in real time to where the problems emerge.

Mr. SMITH. Dr. Fauci, I appreciated your comments on the rush to get to a safe and effective vaccine. And as you pointed out in your testimony and in your comments, and I heard you on the radio talking about this recently, it may not be through the normal channel but we are in an emergency with regards to a vaccine. How quickly could such a vaccine be available?

Dr. FAUCI. Thank you for the question. If you go to a continually emergent situation and all things work well, if we finish the Phase 1 trial, as I predict we will by the end of 2016, and we still have literally thousands of cases into 2017, you could then go into an accelerated Phase 2A/2B clinical trial. If you do the math and the statistics, depending on the number of cases and how effective the vaccine is, in anywhere from 6 to 8 months, you may be able to show that it is, in fact, effective and safe.

At that point, even though it would take maybe a few years to get the final stamp of approval, there are mechanisms of accelerated approval and accelerated access that you could potentially implement, if in fact you have a good safety profile and you have shown efficacy.

So, you could conceivably have it by the end of 2017, which is really rocket speed for a vaccine.

Mr. SMITH. Can I just ask anyone who would like to respond to this, there are about 25,000 children and adults with microcephaly today in the United States. Obviously, there are support groups.

There is a great deal of knowledge that has been gleaned from their experiences. And as I said earlier, the spectrum, it is not unlike, maybe it is not a good comparison but it reminds me of the autism spectrum, the fact that there are people who are severely autistic and some who are higher functioning. And I am wondering if some of those lessons and from those groups like Boston Children's Hospital which has done wonderful work in that area, are you looking to tap that so that we share best practices with these countries which may not have that experience?

Dr. FRIEDEN. Yes, thanks for the question. As you know, Mr. Chairman, from your past work, the Centers for Disease Control and Prevention includes the National Center for Birth Defects and Developmental Disabilities. And in our emergency response, they are fully integrated, including clinical geneticists, who are traveling to Brazil and Colombia to assist with assessment and plans.

We need to learn more about what the spectrum is in this case. As noted, we may well see a broad spectrum of some more severe, some less severe, and this is something that we want to provide all of the expert assistance we can to support women, families and communities that are dealing with this very challenging situation.

Mr. SMITH. Yes, Dr. Pablos.

Dr. PABLOS-MENDEZ. Just to add, one of our partners in the Saving Lives at Birth Initiative is the American Pediatric Association. So, we are working already with them and they can help us bridge domestic lessons to the progress we are deploying internationally.

Mr. SMITH. I appreciate that very much.

I would like to now yield to the distinguished chairman of the Western Hemisphere Subcommittee.

Mr. DUNCAN. Thank you, Mr. Chairman.

There are going to be a lot of folks traveling to Brazil this summer. What steps are being taken in Brazil that you can tell us about? We have even heard calls for canceling the Olympics because people are concerned.

So, what are the Brazilians doing? What are you doing to help? And what do we need to know?

Dr. FRIEDEN. So, Brazil has taken this very seriously. They consider it, I think, an absolute top national priority and, as the other chairman mentioned in his opening remarks, they have deployed hundreds of thousands of people in the response. They are working to reduce mosquito populations. They are trying new forms of mosquito control. They point out that the season of the Olympics is a cooler season, so generally has less mosquito activities, though not none.

But I think from our standpoint at CDC, our role is to give travel advice to people, regardless of why they are traveling. So, whether someone is traveling for the Olympics or any other reason, our advice would essentially be the same. And from the very first days when we had strong evidence suggesting a link between the presence of Zika virus and microcephaly, we have advised that pregnant women strongly consider not going to a place that has Zika spreading.

So, that is our advice from CDC. And that for women who live in such areas, or people who go there, to take really good steps to prevent mosquito bites. And there are things you can do, applying

DEET multiple times a day, mosquito repellant, wearing long-sleeve shirts and long pants, using clothing that has permethrin treatment, so it repels mosquitos, and, to the extent possible, staying indoors within air conditioning, or at least screened and enclosed spaces.

And I think as we learn more in the coming weeks and months, more will be understood about what can be done to keep any risk that might be there to the absolute minimum.

Mr. DUNCAN. I think it will definitely smell like DEET down there, sure enough.

I was in Pucallpa, Peru and there is a mosquito and dengue research project going on and tracking individuals that may have been contracted and where they have traveled to and who else may have been exposed or mosquitos in that area.

A lot of folks in my district are concerned, Mr. Chairman, about unaccompanied children coming north from Latin America. It has been an issue. Now, it is been exacerbated with Zika. And do we need to know anything? I mean how prevalent for a child, a minor to carry a disease? I know you said it has got a very short period where its symptoms are prevalent but are we researching how long an adolescent would carry the disease and whether say they come north of the border and are bitten? Do you see where I am going with that?

Dr. FRIEDEN. Yes.

Mr. DUNCAN. So, what do we need to know about that?

Dr. FRIEDEN. So, we have studied this in a variety of prior outbreaks, as have others. The virus stays in the blood for about a week after people begin to get sick. We don't see long-term persistence. So, unlike for example HIV or hepatitis which can stay in your blood really for life, this is a short-lived virus that doesn't persist in the blood beyond a week. And if you think about the numbers, they are really quite striking. There is a lot of travel from Americans going to Central and South America and the Caribbean on the order of 40 million visits per year.

So, lots of travel. And if you think about the different types of travel, that is a very large number compared to different types of risk.

The one area I would, just to give full information, what we don't yet know is how long the virus can persist in semen. And we are doing studies on that but that is the one area where we might see the potential for transmission through sexual contact for more than a week. And we won't know until we do the studies. That is why we have recommended that for men who have sexual contact with women who are pregnant, that to avoid the transmission of Zika——

Mr. DUNCAN. Right, you had mentioned that earlier. I get that.

So, when Ebola outbreak was happening, we were doing airport screening of folks that had traveled to the African continent, especially those three main countries. Latin America travel is much broader than that. Is there any proposal, any talk about doing airport screening for potential symptoms that you know of?

Dr. FRIEDEN. Yes, as you point out, the situation is very different. We have roughly 20,000 visitors versus 40 million. We have

a disease which is spread from person-to-person in the case of Ebola, whereas it is not with other than the rare sexual contact.

Mr. DUNCAN. The sexual activity, right.

Dr. FRIEDEN. Right. So, I think the situation is really very different in terms of Zika and our goal really is to protect pregnant women. That is the key priority now.

Mr. DUNCAN. Right. So, we have an El Nino going on. It is very wet across the South. The amount of water I have seen in Arkansas, Louisiana, Texas, South Carolina, Alabama, Mississippi, and North Carolina means that there is going to be a lot of standing water in the South this year. That means that mosquitos are going to be very, very prevalent, whether they are in the no-see-um variety or whether they are the tiger variety that you mentioned earlier.

So, what are you proposing to help the States address maybe a mosquito outbreak?

Dr. FRIEDEN. This is exactly what is one of the core components of the emergency supplemental request. We will be issuing grants to States at risk and Southern States, as well as U.S. territories to better control mosquito populations.

Mr. DUNCAN. Right. Historically, that has been a winning strategy against malaria and other with mosquito-borne viruses.

Well, listen, as someone who chairs the Western Hemisphere Subcommittee, who is going to be continually focused on this, who may see congressional travel in that area, individual congressmen are going to be concerned, wanting to know what level of information we have and how can we waylay their fears and the general public that continually travel down in that area.

So, this has been very helpful, Mr. Chairman, and with that, I will yield back.

Mr. SMITH. Chairman Duncan, thank you very much for your questions and for this collaboration of the two subcommittees.

I would like to now yield to Mr. Donovan, the gentleman from Staten Island.

Mr. DONOVAN. Thank you, Mr. Chairman, and thank you panelists for sharing your expertise with us and welcome, my friend, Tom Frieden. It has been a long time. I look forward to visiting you in Atlanta. And thank you for all the work you did for the people of New York City when you were Health Commissioner there. I think we were fighting West Nile at that time. It was in its infancy stage in New York when you were the Health Commissioner.

I know that you need more resources. Until we figure that out, is there an ability for you to redirect some resources that you have to address this?

Dr. FRIEDEN. We will do everything within our power to address the Zika challenge. But the supplemental calls for $828 million for CDC in three broad areas, emergency response in Puerto Rico, which has a significant risk of seeing widespread transmission Zika, support for the continental U.S. for States at risk, including mosquito control diagnostics and a series of other measures, and then international support. And while we can get started with that, we can't do it at scale to the level that we would need and we have already had to curtail some other activities, such as our activities that deal with Lyme disease.

Mr. DONOVAN. I ask that because one of the proudest moments I have had in the short 9 months I have been here is when we passed the 21st Century Cures Act to fund CDC and NIH to come up with remedies and vaccines for some of the diseases that are known in the world.

I also realize that it takes a while, even after you have done your work, for the FDA to approve a lot of these things. Is there any mechanism in place, Tom, that we could help you speed that up, whether it is through legislation or something of that nature?

Dr. FRIEDEN. We have been working very closely with the FDA and in both Ebola and Zika, they have been able to rapidly allow us to use effective test technologies within a day or two of our asking. So, that has worked well.

Dr. Fauci can comment further.

Dr. FAUCI. Yes, we really want to tip our hat to the FDA and how they have helped us with with Ebola. When we really needed to get the vaccine trial out quickly and go from a preclinical to a Phase 1, without cutting corners on safety, they greatly expedited their review to allow us to get the Phase 1 trial done here in the United States and in Europe and in Africa and then we went into a Phase 2 trial.

We are working very closely with them right from the beginning. One of the most productive interactions that you have is that you involve the FDA right from the very beginning of a project. You don't do it and then go to the FDA and see how you can get something approved. They work with us right from the beginning, and that is exactly what they are going to be doing as we start developing things like vaccines for Zika. So, we are very optimistic about that relationship.

Mr. DONOVAN. That is very comforting.

The last comment I have, it isn't really a question but a comment, Dr. Fauci, during your testimony, I was dismayed when you told me that you worked so hard and your colleagues worked so hard to find a vaccine, I think it was for West Nile, and that no pharmaceutical company wanted to produce it because there wasn't a profit. All your doctors take a Hippocratic Oath to serve people. I am just dismayed but thank you for sharing that with us.

Dr. FAUCI. You are welcome. That is frustrating for us because we think in terms of what is good for the public health and the global health. And sometimes when you get involved in things that are profit developing, that comes in and gets in the way of that.

Having said that, I feel confident that from the indications we are currently getting from pharmaceutical companies, that we won't have this problem with Zika.

Mr. DONOVAN. So, we should be blessed that there is a profit in the Zika virus.

Dr. FAUCI. Well, unfortunately, that is a perverse way of doing it but you are quite correct.

Mr. DONOVAN. Thank you. Thank you all.

Dr. PABLOS-MENDEZ. If I may add, this region may have more resources but we are also exploring financial mechanisms that we had used in the past for vaccines, where market failure prevent the final development by the companies. And we have an experience within advanced market commitment that has been done through

the Global Alliance for Vaccines and Immunizations, which allowed the introduction of scale of the pneumococcal vaccines for children.

Mr. SMITH. The chair recognizes the gentleman from Florida, Mr. Clawson.

Mr. CLAWSON. Thank you for coming again, guys and I am going to ask for some quick answers because I have got several questions and I think people are ready to go. Okay?

First of all, it is the same mosquito that carries dengue, chikungunya, and Zika, much of the time. Is that correct?

Dr. FRIEDEN. That is correct.

Mr. CLAWSON. And so is anybody thinking about a genetic therapy fix here? I don't want Frankenstein mosquitos but it seems to me that you get the Trojan horse and the soldiers inside the Trojan horse are going to die with it.

And so as I thought about my own legislation for this obvious problem and being from southern Florida, it seemed to me that genetic fix ought to be something that is thought about and if you all tell me it is practical, then with my team, I am going to keep pursuing what we could do legislatively to motivate that.

Are you all in agreement with me on that?

Dr. FRIEDEN. It is a promising technology. The biggest challenge is scalability and community acceptance.

Mr. CLAWSON. Agreed but companies work all over the world and that acceptance factor might be different as we get closer to the equator. You would agree with that, too, right?

Dr. FRIEDEN. I don't have——

Mr. CLAWSON. In terms of because you have got a bigger outbreak, you have got a bigger problem.

Okay, thank you for that. We have a vaccination for dengue in Brazil. Right?

Dr. FAUCI. Correct.

Mr. CLAWSON. I know they were working on one in southeast Asia for a long time. I don't remember where it got. Do they go quicker on this sort of thing to get vaccines in Brazil? Would Americans that are worried about dengue fever, should they go to Brazil for vaccination or are you all hesitant about the safety of this? It just seems like the obvious question.

Dr. FAUCI. No, actually, that is a good question. There is an approved vaccine in Mexico and Brazil—a dengue vaccine that is about 60-plus percent effective.

Mr. CLAWSON. There are four different types of dengue to my——

Dr. FAUCI. You are correct.

Mr. CLAWSON. And if you get a vaccine for dengue fever in Mexico, would it work in India? That is a different strain and sometimes a different mosquito.

Dr. FAUCI. It is the relative proportion of the serotype that is dominant in a particular area. The one that didn't quite get off the ground in Asia didn't have a good protection against all four serotypes; the one that is in Brazil now appears to cover all four.

Mr. CLAWSON. So, it works better with whatever the mosquito here is and maybe the one adjacent that is closer in the serum, as you say.

Dr. FAUCI. Right. And we actually have a Phase 3 trial that is ongoing that started just about 4 weeks ago in Brazil in collabora-

tion with the Instituto Butantan. The NIH is actually running the trial with them.

Mr. CLAWSON. And is anybody working in Asia now, so that if somebody gets off a plane during the rainy season, in the monsoon in India, they don't bring a different strain to Mexico or Brazil?

Dr. FAUCI. Well, I don't think that it is a question of a different strain because you have four dengue serotypes that are essentially universally seen all over. So, even in India, there will be all four strains. Rather than one strain or the other, it is the one that is dominant.

Mr. CLAWSON. Got it.

Dr. FAUCI. For example, serotype 2 is one of the most problematic ones.

Mr. CLAWSON. Got it. Thank you.

Okay, look, for me that is a big deal. I have had breakbone fever and I don't want number two and then have hemorrhagic complication here, guys.

Dr. FAUCI. Yes.

Mr. CLAWSON. And so, as I think through that from my own experience, I say okay, in a world of international travel, the second time is going to be worse. I am in the 50 and older crowd, right, which makes my liver even more susceptible to swelling. So, we also have to think about that global nature of this. Am I right about that or am I missing the boat here?

Dr. FAUCI. You are correct.

Mr. CLAWSON. Okay. My idea, our idea legislatively was we could always use government money here. It seems to me that as long as, to Mr. Donovan's point, as long as a drug companies see a profit motive, and I am always worried about that in Zika because I have got one of the few districts that might be actually impacted here, it is not going to get impacted in New Hampshire but it could be impacted in my district, Naples. Nonetheless, I mean if we gave somebody tax credits for their research and development in order to expedite research into battling this virus or coming up with a vaccine, do you see any downside on that, trying to accelerate the private sector to jump in the game here? Because it feels to me like they sat out dengue fever. It feels like they are sitting out chikungunya. And we don't want them to sit out Zika. Am I right about all of that?

Dr. FAUCI. Incentives to the pharmaceutical companies are often helpful in getting themselves engaged in this work. We have another way to incentivize them. What we do at NIH is de-risk their investment. We do a lot of the work that they would otherwise pay for themselves so that their investment risk is less. Some companies take the vaccine from the concept to the product. They don't need anybody. They don't need the NIH. They don't need anybody. But when something is a public health imperative, and they are not interested, if we push the envelope to the point where we can say we have a product that we know is good, it is safe, and it is immunogenic, they are much more enthusiastic about getting involved because we have already made a major investment.

In addition to what you said, which I agree with, that is a good way to incentivize them.

Mr. CLAWSON. Can I have one more question, Mr. Chairman? One more question.

So, we always think about these diseases as if they were malaria, which means outdoor nighttime. These are indoor daytime mosquitos. And so spraying, whenever I see the spray trucks I say well that is a wasted bullet. On the other hand, in our country and in my district, we don't have as much water sitting around, fresh water sitting around like you find in the Caribbean or in Brazil. If we do a good job on making sure we don't have a lot of pooling water around, is that enough? Are we going to be okay until there is a vaccination?

Dr. FRIEDEN. It is really going to depend on the local environment.

Mr. CLAWSON. How about southwest Florida?

Dr. FRIEDEN. Well, this is one of the reasons we need the supplemental, to give resources so that we can look at mosquito populations, track them, analyze them, and then sometimes larviciding can have a very major impact on reducing mosquito populations.

Your point is quite correct that the outdoor spraying may have limited impact, if any, on this mosquito population but we are looking at different ways of doing mosquito control. And in some circumstances, what they have done in Australia, for example, is used targeted indoor residual spraying for this particular mosquito with, as far as we have seen, some pretty effective results. But all of that is quite complex to do.

Mr. CLAWSON. And let me see, just taking off on that point so that I understand it correctly. Because again, we want to get in the game here, legislatively. So, I am not asking to just take your time here.

Like a lot of things, it always impacts the poor; life is never fair. And so in my house, I have air conditioning. If I see a mosquito inside, I say to myself it is not chikungunya, it is not Zika. So, if I get bit, I don't have to worry about it but someone else who may not be able to afford that is more at risk.

Am I right about that? Do I understand the information correctly?

Dr. FRIEDEN. You are exactly right.

Mr. CLAWSON. But that should drive some of our policy here as well. Pooling water at my house is not as much of a problem as it is going to be at someone less fortunate. Am I right about that, economically speaking?

Dr. FRIEDEN. If we look at a study done by CDC doctors and scientists of a dengue outbreak in Brownsville-Matamoros in South Texas a few years back, the rate of infection was eight times higher in Matamoros than it was in Brownsville.

Mr. CLAWSON. Really?

Dr. FRIEDEN. And the two driving forces for that were air conditioning——

Mr. CLAWSON. Really?

Dr. FRIEDEN [continuing]. Reduced people's risk 15-fold and smaller house plots, which increased crowding and increased risk 7-fold.

Mr. CLAWSON. Right. And then even if they have air conditioning, they often don't have it in the bathroom, where the water

is or in the kitchen where the water is. Am I right about that, too? So, it complicates it.

Dr. Pablos-Mendez, is there anything on my line of questioning that you have heard me say? [Speaking foreign language.]

Dr. PABLOS-MENDEZ. [Speaking foreign language.]

You are so knowledgeable and we discussed this last time when we were talking about dengue. You were almost prescient that clearly this scenario deserves attention.

I just want to report that under the President's Malaria Initiative, we work with the Gates Foundation and many other partners on an Innovative Vector Control Consortium. We are interacting with industry. We are looking at new insecticides, new tools.

That effort was focusing on Africa, malaria but that capability can be deployed to address this need in the region.

Mr. CLAWSON. Can I interrupt just one? You are making a great point. I got bit at 9 o'clock in the morning in an auto parts plant that you are never going to air condition, right? So, the work environment is an area that we have got to keep in mind. I think that is a great point.

Dr. PABLOS-MENDEZ. And you are correct also, that is usually the poor. It is northeast section of Brazil, a poor area, more tropical area. So yes, there are local conditions that make it more likely that you will get the disease.

The other point I would like to just mention is of course we do have for a while now the Orphan Drug Act that provides so many incentives for industry to develop diseases where otherwise market failure would prevent them.

So, we have some tools and we have different markets, different diseases, as Dr. Fauci has alluded. We are looking at how we are going to work in that space so that industry is engaged not only in finally developing these products but in scaling them up and so that they can reach the poor, in particular.

Mr. CLAWSON. You all keep talking. You all are great. And we need to spend some money on this. It is real-life impact on a lot of people, so thanks for what you are doing.

And thanks for being so patient with me here asking all these questions.

Mr. SMITH. Thank you very much, Mr. Clawson. Just two final quick questions.

First, I remember my first trip to El Salvador in the early 1980s being struck by how many people—I remember being in Ambassador Corr's home, President Duarte was actually there, and there wasn't a screen in the place that I can recall. And for many trips to Central and South America, very often, people do not have screens. And even our Foreign Service Officers, obviously, in their homes, they are at risk, it would seem to me, if there are no screens.

Is that something that is being looked at to promote screening as one of the best practices?

Secondly, there are press reports that some NGOs are planning to exploit child disability and the potential link of microcephaly with Zika to promote abortion. And I am wondering and I am hoping, and maybe you can verify, that none of the $1.8 billion and the President's strategy does not have that agenda.

Dr. FRIEDEN. Thank you very much. Yes, we do believe screens may play a role. There are also permethrin treated screens that may be even more effective and this is something that we are very actively looking at now.

I can assure you that the emergency supplemental request does not contain any proposal to change in any way current policy regarding abortion.

Mr. SMITH. Yes, Doctor?

Dr. PABLOS-MENDEZ. Well thank you very much. Indeed, USAID fully advised by the U.S. law, which includes a Helms amendment that precludes us from using any foreign assistance resources to pay for the performance of abortion as a method of family planning or to motivate, of course, any person to practice abortions. We don't do abortions.

Mr. SMITH. And of course the Siljander amendment makes clear that even the promotion is not——

Dr. PABLOS-MENDEZ. Correct, even the promotion.

The only thing I will say is that because we are so careful with this, we monitor this very carefully everywhere we do work. Part of the request includes some—request because we will need to have staff deployed to ensure that our partners and the work that is deployed does not go into areas the law does not let us go.

Mr. SMITH. I appreciate that.

You have been tremendous in providing information to both subcommittees, insights and I thank you for your service, which is extraordinary, and for allowing us to benefit from that expertise and that knowledge.

The hearing is adjourned.

[Whereupon, at 3:22 p.m., the subcommittee was adjourned.]

# APPENDIX

## Material Submitted for the Record

**JOINT SUBCOMMITTEE HEARING NOTICE**
**COMMITTEE ON FOREIGN AFFAIRS**
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

**Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations**
**Christopher H. Smith (R-NJ), Chairman**

**Subcommittee on the Western Hemisphere**
**Jeff Duncan (R-SC), Chairman**

February 10, 2016

**TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS**

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held jointly by the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations and the Subcommittee on the Western Hemisphere in Room 2172 of the Rayburn House Office Building (and available live on the Committee website at http://www.ForeignAffairs.house.gov):

**DATE:** Wednesday, February 10, 2016

**TIME:** 1:15 p.m.

**SUBJECT:** The Global Zika Epidemic

**WITNESSES:** Tom Frieden, M.D.
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services

The Honorable Ariel Pablos-Mendez, M.D.
Assistant Administrator
Bureau for Global Health
U.S. Agency for International Development

**By Direction of the Chairman**

*The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.*

# COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON Africa, Global Health, Global Human Rights, and International Organizations the Western Hemisphere HEARING

Day *Wednesday* Date *February 10, 2016* Room *2172 Rayburn HOB*

Starting Time *1:16 p.m.* Ending Time *3:22 p.m.*

Recesses [ *1* ] (*2:19* to *2:51*) (____ to ____) (____ to ____) (____ to ____) (____ to ____) (____ to ____)

**Presiding Member(s)**

*Rep. Chris Smith*

*Check all of the following that apply:*

Open Session [✓]
Executive (closed) Session [ ]
Televised [✓]

Electronically Recorded (taped) [✓]
Stenographic Record [✓]

**TITLE OF HEARING:**

*The Global Zika Epidemic*

**SUBCOMMITTEE MEMBERS PRESENT:**

*Rep. Ami Bera, Rep. Jeff Duncan, Rep. Ron DeSantis, Rep. Scott DesJarlais, Rep. Albio Sires, Rep. Dan Donovan, Rep. Ted Yoho, Rep. Alan Lowenthal, Rep. Curt Clawson, Rep. Mark Meadows*

**NON-SUBCOMMITTEE MEMBERS PRESENT:** *(Mark with an * if they are not members of full committee.)*

*Rep. Tulsi Gabbard, Rep. Michael Burgess**

**HEARING WITNESSES: Same as meeting notice attached? Yes [✓] No [ ]**
*(If "no", please list below and include title, agency, department, or organization.)*

**STATEMENTS FOR THE RECORD:** *(List any statements submitted for the record.)*

***Questions for the record from Rep. Bera for Dr. Pablos-Mendez***
***Article by Dr. Dina Fonseca on mosquito control and Zika, submitted by Rep. Chris Smith***

**TIME SCHEDULED TO RECONVENE** _____
**or**
**TIME ADJOURNED** *3:22 p.m.*

Gregory B. Simpkins
**Subcommittee Staff Director**

**Questions for the Record Submitted by Representative Ami Bera**
**for Assistant Administrator Ariel Pablos-Mendez**
**House Committee on Foreign Affairs**
**Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations**
**Subcommittee on the Western Hemisphere**
**February 10, 2016**

Throughout many of the areas hardest hit by Zika, contraception can be difficult to access and pregnancy is often not a choice. Almost 19 million women in Zika affected areas have an unmet need for family planning services and 900,000 infections are expected among women of reproductive age. As we continue to respond to the Zika epidemic it's critical that women have the tools they need to make the best decision for their families. We have an opportunity right now to expand access to comprehensive health care for women in the region.

**Question:**

What is being done and how can Congress help support efforts to ensure that all women have the tools they need to voluntarily delay pregnancy?

**Answer:**

[Response not received by time of printing]

**Question:**

Within the emergency supplemental funding request for Zika, are there dedicated resources for contraception and reproductive health care?

**Answer:**

[Response not received by time of printing]

**Question:**

What programs and organizations are best situated to deliver those services and what kind of support do they need?

**Answer:**

[Response not received by time of printing]

**Question:**

We expect that the Zika epidemic will create a higher demand for reproductive health services. Some countries, particularly Venezuela, are already encountering a shortage of contraceptives. What is being done to ensure that there is an adequate supply of contraception to meet the needs of families throughout the region?

**Answer:**

[Response not received by time of printing]

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

**Steps for effective mosquito control in response to a potential Zika virus outbreak**

Dina M. Fonseca, Professor of Entomology, Rutgers University, New Brunswick, NJ

Although when mentioning mosquito control in the US many envision post WWII truck mounted DDT applications for control of yellow fever and malaria, in reality yellow fever, **a deadly imported disease transmitted by the same invasive mosquitoes that vector Zika virus**, was eradicated from the US significantly earlier (in 1905, Box 1). In fact this achievement occurred 5 short years after US Army Major Walter Reed's team made the fundamental scientific discovery that a bite from *Aedes aegypti* mosquitoes exposed to yellow fever patients would sicken a healthy volunteer.

Critically, 4 of the **5 basic steps** implemented by the US Army in Cuba, southern US and Panama for yellow fever control targeted the immature stages (larvae) of *Aedes aegypti*. These were **(1)** small pool and container drainage; **(2)** brush & grass cutting; **(3)** larviciding; **(4)** window/door screening; **(5)** killing of adult mosquitoes (mostly by hand).

**These same strategies can also work today.** However, instead of the military campaigns of yesteryear, urban mosquito control requires clear and extensive involvement by residents using active novel engagement strategies based on mutual trust[1].

**BOX 1 – History of Mosquito Control – the early years**

**1878** – first report that mosquitoes can transmit disease agents.
**1898** – first demonstration that mosquitoes transmit malaria.
**1900** – first demonstration that mosquitoes transmit yellow fever.
**1902** – control of urban mosquitoes with intensive sanitation campaigns achieves **control of yellow fever in Cuba.** US Army forces leave in 1902. Sanitation efforts extended to the US.
**1903** – Hawaii's first epidemic of dengue fever.

**1904** – **Dr. John B. Smith** of Rutgers University explains to the NJ Senate the habits and life history of the saltmarsh mosquito, *Aedes sollicitans*. Consequent ditching and draining of salt marshes is shown to be an effective strategy to control this tremendous nuisance.

**1904** – **Panama Canal**: Creation of the Isthmian Canal Commission – U.S. Medical Corps, U.S. Army, U.S. Navy - tasked to control malaria and yellow fever in Canal Zone. By 1909 **local eradication** of the yellow fever mosquito, *Aedes aegypti,* and of the yellow fever virus was achieved. 75% decline in malaria cases.

**1905** – Last epidemic of yellow fever in the US (New Orleans).
**1907** – **dengue fever linked to *Aedes aegypti*.** After 1911 sanitation measures in Hawaii eliminate dengue (until 1943 when *Ae. aegypti* is reintroduced).

**1912** – NJ State Legislature passes the **County Mosquito Extermination Commission Law** creating the first organized Mosquito Control Programs in the US. The concept is also embraced by states with mosquito nuisance problems and strong leadership.

Additionally, it is important to acknowledge that across the US remaining state and local organized mosquito control's first (Box 1) and primary mission is to manage **nuisance** mosquitoes, specifically salt marsh mosquitoes and inland marsh mosquitoes. Case in point, when West Nile virus (WNV) arrived in NYC in 1999, the city did not have an organized mosquito control program and help had to arrive from neighboring states. But organized mosquito control in NJ, PA, etc. also did not have standard operating procedures to control mosquitoes in wastewater treatment facilities and storm water catch basins, the high organic water were urban *Culex* thrive[2]. In 2000, CDC funded research for the control of urban mosquitoes and infused funds into states for urban mosquito control. Unfortunately, those funds were not maintained and many of the programs were not sustainable.

To date it is estimated that over 1,500,000 residents of the contiguous 48 have been infected with WNV[3] as the disease progressed across the US largely unabated. This fact may be fuelling some of the public concerns over the potential spread of Zika virus (ZIKV) in the US. However, WNV is primarily a bird disease vectored by bird biting *Culex* among urban birds, such as robins and house sparrows. Bird biting mosquitoes infected with WNV sometimes bite humans leading to human cases of WNV[4]. It is important to emphasize that **controlling a vector-borne disease like WNV that circulates primarily among non-humans (and occasionally infects humans) is very different from controlling a disease such as Zika.** This is because it is impossible to isolate a significant amount of infected wild hosts from mosquitoes. In contrast, if careful information and resources are made available, infected human patients can be kept away from mosquitoes, therefore preventing continued transmission. To the best of our knowledge, outside of Africa ZIKV only infects humans and is vectored among humans by urban *Aedes* mosquitoes. Urban *Aedes* also vector dengue and chikungunya, two other VBDs expanding across the New World tropics for which there are no vaccines. With no vaccines available, mosquito control is the single most effective away to prevent or stop transmission of Zika, dengue and chikungunya. Rare events of human-to-human transmission do not invalidate this conclusion.

After consulting colleagues, carefully reviewing the literature, and based on the extensive work we developed in NJ funded by a USDA-ARS Area-wide program to manage the Asian tiger mosquito, *Aedes albopictus* (http://asiantigermosquito.rutgers.edu/), a potential vector of ZIKV in the highly urbanized NE-US, I conclude there are 4 issues that require immediate attention:

(1) Investment should be made in building or rebuilding sustainable professional urban mosquito control. Even states with extensive local programs, such as NJ, FL, CA, will require funds to respond to a Zika outbreak, both for surveillance and viral testing of mosquito pools. New professionals will require increased training and continuing education programs.

(3) Development of effective ways to disseminate information on how to reduce or eliminate small pools of water in private properties where immature mosquitoes develop, and on the need to allow access to professionals from mosquito control programs. This is an area where mosquito control, public health, and enforcement must operate in solidarity.

(5) Better control of new introductions of organisms into the US. The first highly domesticated *Culex* and *Aedes* species, likely arrived shortly after (or maybe inside) the *Pinta, Niña* and *Santa Maria*. Significant introductions of new mosquito species started again in the 1980's associated with the traffic of used tires (3 new *Aedes* have arrived since 1985). Of note, new introductions of existing species such as the primary *Aedes* vectors of Zika, may be resistant to standard insecticides, even to DDT, already upon arrival (DDT is still in use in other countries).

(2) Investment in countrywide and worldwide insecticide resistance (IR) testing and mapping. IR can significantly impact control strategies and outcomes while releasing harmful and useless insecticides to the environment. Increasing movement of invasive mosquitoes associated with humans requires increased vigilance and international cooperation to manage IR.

(4) New strategies for mosquito surveillance and control such as development and optimization of new traps, insecticides with new physiological targets, strategies for auto-dissemination of insecticides, lethal ovitraps and genetically modified mosquitoes (sterile insect techniques, release of insects with dominant lethality, or *Wolbachia* infected males). Many of these new methods are on the cusp of becoming reality, but funding is needed in order to carry out area-wide field efficacy trials to assess their value in integrated mosquito management programs.

**Literature Cited**


1 Healy, K., Hamilton, G., Crepeau, T., Healy, S., Unlu, I., Farajollahi, A. & Fonseca, D. M. Integrating the public in mosquito management: active education by community peers can lead to significant reduction in peridomestic container mosquito habitats. *PLoS One* **9**, e108504 (2014).

2 Rochlin, I., Ninivaggi, D. V., Hutchinson, M. L. & Farajollahi, A. Climate change and range expansion of the Asian tiger mosquito (*Aedes albopictus*) in Northeastern USA: implications for public health practitioners. *PLoS One* **8**, e60874 (2013).

3 Lindsey, N. P., Staples, J. E., Lehman, J. A., Fischer, M. Surveillance for human West Nile virus disease - United States, 1999-2008. *Morbidity and mortality weekly report. Surveillance summaries* **59**, 1-17 (2010).

4 Farajollahi, A., Fonseca, D. M., Kramer, L. D. & Marm Kilpatrick, A. "Bird biting" mosquitoes and human disease: a review of the role of *Culex pipiens* complex mosquitoes in epidemiology. *Infect Genet Evol* **11**, 1577-1585 (2011).